A STUDY TO ASSESS THE EFFECTIVENESS OF POMEGRANATE POPSICLES ON INFLAMMATION OF THE ORAL MUCOSA AMONG PATIENTS ON CHEMOTHERAPY IN A SELECTED HOSPITAL AT CHENNAI

M.SC (NURSING) DEGREE EXAMINATION
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A dissertation submitted to

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CERTIFICATE

This is to certify that this dissertation titled **"A STUDY TO ASSESS THE EFFECTIVENESS OF POMEGRANATE POPSICLES ON INFLAMMATION OF THE ORAL MUCOSA AMONG PATIENTS ON CHEMOTHERAPY IN A SELECTED HOSPITAL AT CHENNAI."** is a bonafide work done by Mr. Chandra Rajan Enoch Snowden Rose, Venkateswara Nursing College, Thalambur, Chennai-600130, submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the University rules and regulations towards the award of the degree of Master of Science in Nursing Branch- I, Medical Surgical Nursing under our guidance and supervision during the academic period from 2014-2015.

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Oh, give thanks to the Lord, for He is good! For His mercy endures forever.
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Who remembered us in our lowly state, For His mercy endures forever;
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- Holy Bible

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LIST OF ABBREVIATIONS

N	Number of sample
SD	Standard Deviation
S	Significant
NS	Not significant
f	Frequency
t	Student ‘t’ test
NA	Not association
%	Percentage
GLOBOCAN	Global Burden of Cancer Study
W.H.O	World Health Organisation
OMDQ	Oral Mucositis Daily Questionnaire
OMQoL	Oral Mucositis-specific Quality of Life
OM	Oral Mucositis
QOL	Quality of Life
HRQOL	Health-Related Quality of Life
TPN	Total Parenteral Nutrition
PJ	Pomegranate Juice
PE	Pomegranate Extracts
PSA	Prostate Specific Antigen

ABSTRACT

STATEMENT OF THE PROBLEM

"A Study to Assess the Effectiveness of Pomegranate Popsicles on Inflammation of the oral mucosa among Patients on Chemotherapy in a Selected Hospital at Chennai."

OBJECTIVES OF THE STUDY

- To evaluate the effectiveness of pomegranate popsicles on oral mucositis among patients receiving chemotherapy in experimental and control group.
- To find out the association between the post-test level of oral mucositis among patients receiving chemotherapy with their selected demographic variables.

METHODS

A Quantitative Research approach was adopted for this study. A review of literature was done on studies related to oral mucositis as a side effect of chemotherapy, studies related to the prevention of oral mucositis by cryotherapy and studies related to pomegranate and its effect on cancer. The conceptual framework opted for this study was based on the Model of Widenbach's helping art of clinical nursing theory (1969), in order to achieve the objectives of the study. The Research design adopted was post test only control group design. The tool adopted for the study is standardized "WHO Oral Mucositis Scale". The tool was validated by 5 experts.

A pilot study was conducted before under taking the main study. The main study was conducted in Dr.Kamakshi Memorial Hospital Pvt.Ltd., Radial Road, Pallikaranai, Chennai, among 60 samples of first cycle chemotherapy patients. Purposive sampling technique was used to

select 30 samples into experimental group and 30 patients into control group. The study lasted for a period of 4 weeks during which, the first and second weeks subjects were taken as experimental group and in the third and fourth weeks subjects were taken as control group. Demographic data was collected from the subjects. Intervention with pomegranate popsicles was given to the experimental group whereas the control group followed the routine mouth was with fresh water three times a day. And post test level or oral mucositis was assessed on the seventh day. The data was analysed by descriptive and inferential statistics, the hypothesis was tested, the objectives were achieved and the result was presented.

MAJOR FINDINGS OF THE STUDY

The findings of the study revealed the analysis post test scores of oral mucositis level on first cycle chemotherapy patients. The analysis revealed that in experimental group 23 (77%) of them did not develop oral mucositis, 7 (23%) of them had mild level of oral mucosits and none of them had moderate, severe or intravenous feeding level of oral mucositis. In control group none of the patients had sever or intravenous feeding level of oral musocitis, 6 (20%) of them had moderate level of oral mucositis, 7 (23%) of them had mild oral mucosits and 17 (57%) of patients did not develop oral mcositis.

In the experimental group the mean score of oral mucositis is 0.23 and Standard Deviation 0.430. In the control group the mean score of oral mucositis is 0.63 and Standard Deviation 0.809. The paired ‘t’ test gave a ‘t’ value of 2.392, at df=58, the p value was 0.020019 which is significant at $p < 0.05$ level. Therefore pomegranate popsicles proved to have a significant effect on preventing inflammation of the oral mucosa among chemotherapy patients.

Among chemotherapy patients the demographic variables such as, Age, Sex, Educational Status, Occupation, Type of Activity, etc. had no significant association with post test oral mucositis level, whereas what the patient used for brushing and the use of chat items in the diet showed to have a significant association with post test level of oral mucositis at $p < 0.05$ level.

CONCLUSION

This study assessed the effectiveness of pomegranate popsicles on oral mucositis induced by chemotherapy. From the results of the study, patients who were intervened with pomegranate popsicles were 20% less likely to develop oral mucositis.

Thus nurses can give pomegranate popsicles to patients undergoing chemotherapy to reduce oral mucositis induced by chemotherapy as it is, one of the best, non-pharmacological and cost effective intervention proved to reduce oral mucotitis among chemotherapy patients.

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CHAPTER – I
INTRODUCTION

"An ounce of prevention is worth a pound of cure."
- (Benjamin Franklin)

"We live in a super-fast age where the Internet has shrunk the world dramatically and people are connected 24×7. Multitasking is the order of the day and we struggle to fulfill our responsibilities to our employers, parents, spouses, children, clients and many others. In this melee, we too often forget to spare time to take care of our health. Health is one of the most important assets we human beings have, it permits us to fully develop our capabilities and live our lives to the fullest. If this asset erodes or is not taken care of, it can cause physical and emotional weakening and be an obstacle in the lives of people.

Our altered lifestyle habits make us vulnerable to many diseases like obesity, diabetes, hypertension, heart disease, cancer, and stroke. Among the many diseases which deteriorate health, cancer has a prominent place. The patient's prognosis, treatment modalities and side effects of treatment for cancer are long-lasting issues that can severely affect a person's quality of life.

According to the Data gathered for the Leading Causes of Death by the **Centers for Disease Control and Prevention** in 2011, cancer has got the second place for the world's leading cause of death. There were an estimated 14.1 million cancer cases around the world in the year 2012, of these 7.4 million cases were in men and 6.7 million cases in women. This number is expected to increase to 24 million by 2035. This growing cancer burden was a key focus of the United Nations General Assembly High-Level Meeting on Non-Communicable Diseases on September 2011 in New York.

A person diagnosed with cancer may undergo surgery, radiation or chemotherapy as a management of cancer, among which chemotherapy is the commonest treatment modality. It controls the uncontrolled division of cells by interfering with cellular function and reproduction. Chemotherapy is used to reduce tumour size preoperatively, to destroy any remaining tumour cells postoperatively, or to treat some forms of leukaemia. Cells with rapid growth rates such as bone marrow, epithelium, hair follicles and sperm are very vulnerable to damage due to chemotherapy.

The rapid proliferation rate of epithelial lining of oral cavity makes it susceptible to the effect of chemotherapy resulting in oral mucositis. Oral complications that arise with chemotherapy and/or radiation therapy include xerostomia (dry mouth), dental caries, loss of taste, osteoradionecrosis, oral mucositis and bacterial, fungal, or viral infection mainly in neutropenia patients. Among these oral mucositis is a major nonhematologic complication of cytotoxic chemotherapy and radiotherapy associated with significant pain, dyseugia, odynodysphagia, subsequent dehydration and malnutrition.

Although the exact pathophysiology of mucositis may not be fully elucidated, it is thought to have two main mechanisms: direct mucositis and indirect mucositis, caused by chemotherapy and/or radiation therapy.

Direct Mucositis - The epithelial cells of the oral mucosa undergo rapid turnover every 7 to 14 days, making these cells susceptible to effects of cytotoxic therapy. Both chemotherapy and radiation therapy can interfere with the maturity and growth of epithelial cells, causing changes in normal turnover and cell death.

Indirect Mucositis **-** It is caused by indirect invasion of gram-negative bacteria or fungal species. Patients are usually at increased risk for oral infections when they are neutropenic. The onset of oral mucositis secondary to myelosuppression varies, depending on the timing of neutrophil count associated with the chemotherapy agent administered, but typically develops anywhere around 10 to 21 days after chemotherapy.

Cancer patients who are undergoing chemotherapy usually show signs of mucositis four to five days after beginning of treatment, reaching a peak around 7^{th} day to 10^{th} day, and then slowly improving over the course of a few weeks. As a result of cell death in reaction to chemotherapy or radio-therapy, the mucosal lining of the mouth becomes thin, slough off, then become red, inflamed and ulcerated. The ulcers become covered by a yellowish white fibrin clot called a pseudo membrane. These ulcers may range from a size of 0.5 cm to greater than 4 cm.

Oral mucositis can be severely painful related to the extent of the tissue damage. The pain is often described as a burning sensation accompanied by reddening. The patient may experience trouble in speaking, eating, or even opening the mouth because of pain. An alteration in taste perception (dysgeusiaor) is commonly noted, especially for those who are receiving a concomitant radiation therapy to the neck and mouth area. Taste blindness or an altered sense of taste, is a temporary condition that occurs because of effects on taste buds that are mostly located in the tongue. Sometimes, only a partial recovery of taste occurs. Common complaints include, food tasting too sweet or too bitter or having a continuous metallic taste.

Many preventive measures which are directed towards aetiology of oral mucositis have been currently gaining importance. Preventing a complication beforehand is much easier and less costly than treating it. In this context, cryotherapy (oral cooling using ice) has become a cheap and readily applicable method in preventing or decreasing oral mucositis developing due to chemotherapy. Cryotherapy causes a local vasoconstriction, which in turn reduces blood flow in oral mucosa and reduces the amount of drug distributed to cells, thereby reducing the incidence of oral mucositis.

In conclusion, severe oral mucositis is a common cause of morbidity in patients undergoing chemotherapy. It may be further complicated by an infection or bleeding and it becomes more difficult for patients to maintain their oral hygiene. Higher symptoms burden will have a profound impact on patient's quality of life and level of psychological distress. For minimizing the symptoms of oral mucositis applying oral ice cubes is a cheap, readily applicable and effective method.

1.1 NEED FOR THE STUDY

Projections based on **Global Burden of Cancer Study (GLOBOCAN) 2012** estimates predict a substantive increase to 19.3 million new cancer cases per year by 2025, due to the rapid growth and ageing of the global population. More than half of all cancers (56.8%) and cancer deaths (64.9%) in 2012 occurred in less developed regions of the world, and these proportions will increase further by 2025.

In the Indian scenario, Cancer is the second most common disease in India responsible for maximum mortality with about

0.3 million deaths per year. This is owing to the poor availability of prevention, diagnosis and treatment of the disease. **GLOBOCAN 2012** estimates 1.1 million new cancer cases, indicating India as a single country (of the 184 countries) contributing to 7.8% of the global cancer burden; mortality figures were 682830, contributing to 8.33% of global cancer deaths; and the five year prevalence was 1.8 million individuals with cancer corresponding to 5.52% of global prevalence. As per Indian population census data, the rate of mortality due to cancer in India was high and alarming with about 806000 existing cases by the end of the last century.

In Tamil Nadu, projections from a cross sectional study carried out by **Selvaraj J et al 2014** exploring the patterns and trends of the cancer incidences in the western regions including Coimbatore, Erode, Tiruppur, Salem, Namakkal and Nilgiris confirms that cancer is an important cause of adult deaths. The cancer cases were segregated district-wise for specific cancer sites and the age-standardized incident rates were calculated for different age groups. More than 70% of fatal cancers occurred during the productive ages of 50-74 years of age. Among all districts in Tamil Nadu, the highest frequency of cancer cases was observed in Coimbatore district and least in Nilgiris district.

In Chennai, the total cancer burden is predicted to increase up to 32% by 2012–16 compared with 2002–06, with 19% due to changes in cancer risk and further 13% due to the impact of demographic changes, states a research carried out by **R. Swaminathan et al 2011** of the Division of Epidemiology and Cancer Registry, Cancer Institute (WIA), Chennai. The annual cancer burden predicted for 2012–16 is 6100 for Chennai, translating to 55,000 new cancer cases per year statewide in Tamil Nadu.

Dr.Kamakshi Memorial Hospital a Super speciality hospital providing services to all the divisions of health care including cancer care pioneered not only in advanced scientific management of diseases but also in equipping with modern technologically advanced Gadgets. Their success rates are comparable to the best centers in the world. According to the hospital statistics 2648 patients have been treated for cancer in 2013, out of which 24% of patients underwent radiation therapy, 60% of patients underwent chemotherapy, and 16% of patients underwent brachytherapy. The statistics showed a similar trend with majority of the patients on chemotherapy the year following also.

Statistics from ***Cancer Treatment and Survivorship Facts and Figures 2012-2013*** shows that 31% of Breast Cancer patients undergo chemotherapy, 50% of Colon Cancer patients undrgo chemotherapy, 62% of Rectal Cancer patients undergo chemotherapy and 20% Non-Small Cell Lung Cancer patients are undergoing chemotherapy. Similarly in Testicular Germ Cell Tumor patients 67% are undergoing chemotherapy and in Uterine Cancer 33% are on chemotherapy. Chemotherapy alone, or in combination with radiation, is often given to patients with advanced stage of the disease.

Oral mucositis is one of the most common adverse reactions encountered in chemotherapy as well as in, radiation therapy for head and neck cancers, and is often debilitating. It may even limit the patient's ability to tolerate chemotherapy or radiation therapy, as the nutritional status of the patient is compromised. It may drastically affect the cancer treatment as well as patient's quality of life. The incidence and severity of oral mucositis will vary from patient to patient. It will also vary from treatment to treatment.

According to an US Oncological Review on Chemotherapy-induced Oral Mucositis by **Raj Sadasivan 2010** the incidence of oral mucositis in cancer patients varies widely. In patients receiving high-dose of myeloablative chemotherapy, the incidence rate of oral mucositis is nearly 100%. The incidence rate is also high in patients undergoing head and neck cancer treatments; especially if they are receiving concurrent chemoradiotherapy the incidence rate of oral mucositis may be as high as 90%. In general, the incidence rate of oral mucositis in cancer patients undergoing chemotherapy at standard doses is 40–60%. In patients undergoing chemotherapy at standard doses, oral mucositis generally presents itself as grades 1 and 2 rather than grades 3 and 4. Even with these early grade presentations, patients usually will often not report it to their physicians or to their family members. Patients can rapidly become dehydrated, malnourished and deteriorate to the severity of needing hospitalization. It was noted that 16% of patients with oral mucositis developed due to chemotherapy required hospitalization.

Oral mucositis can lead to septicemia, bacteremia and fungemia when the patient is in neutropenia. Early diagnosis could lead to a change in the schedule of treatment and alleviating mucositis and its complications. These findings have created a broader understanding of oral mucositis and the need to treat it early in its presentation, rather than leaving it as an unmet medical need. Thus assessing the nature of oral mucositis becomes essential among patients receiving chemotherapy.

Cryotherapy is an inexpensive and readily available treatment for oral mucositis. Studies evaluating cryotherapy noted benefits in patients who chewed on ice before each chemotherapy

infusion. The incidence of oral mucositis and the degree of oral mucositis (incidence of grade 3 and 4) were mildly diminished with cryotherapy.

In a comparative study by **Sue Nikoletti et al 2005** on plain ice and flavoured ice for preventing oral mucositis associated with use of chemotherapy. Findings from 67 patients revealed that when participants used standard care alone, they were significantly more likely to experience symptoms of oral mucositis than when they used either plain or flavoured ice. Odds ratios were at least threefold higher for standard care alone, varying according to the instrument used. The two main concerns reported were the taste of flavoured ice and the time required to complete the cryotherapy interventions. Side effects such as nausea, sensitivity and headache were reported more frequently for flavoured ice. The study recommended further research with unsweetened fruit juices to see effectiveness.

In a randomised controlled trial by **Svanberg A et al 2010** to investigate if oral cryotherapy during chemotherapy reduces oral mucositis and improves nutrition. There were significantly fewer patients in the experimental group with oral mucositis grade 3-4 than in the control group and significantly lower number of days in the hospital. No significant difference could be found with regard to infection rate. Oral cryotherapy reduced oral mucositis, number of hospital days, and the need for total parenteral nutrition and resulted in a better nutritional status of the patient.

A study conducted by **Castelino Flavia et al 2011** focusing on prevention of oral mucositis among cancer patients receiving chemotherapy using plain versus flavored ice cubes to improve their quality of life with fewer complications. The check list scores of the

patients showed that there is a difference in the experiences of the patients while sucking plain ice cubes and flavored ice cubes. As a whole the results showed that the flavored ice cubes were effective in preventing mucositis and the patients were in favor of the flavored ice cubes.

At present there is no standard precaution to prevent or treat oral mucositis developed as a side effect of cancer management and no intervention is completely successful at preventing or treating oral mucositis. The several solutions, drugs and methods used and studied in the prophylaxis and therapy of chemotherapy or radiotherapy-induced oral mucositis reflects the need of new, more efficient tools in the management of this complication. Current studies and our increasing understanding of the etiology and pathogenesis of oral mucositis will lead to new approaches to the management and improved quality of life for these patients.

Further intensive research through well-structured clinical trials to obtain the best scientific evidence over the standard therapy for oral mucositis is necessary to attain ideal parameters for radiotherapy and chemotherapy. The above literatures and the recommendation for further research with frozen fruit juices motivated the investigator to undertake this study. As ice cubes can be made readily available and cheaper, people undergoing chemotherapy may effectively use this in their due course of therapy. Keeping the above views in mind the investigator had an intense curiosity to assess the effectiveness pomegranate popsicles over oral mucositis among the patients receiving chemotherapy

1.2 STATEMENT OF THE PROBLEM

A Study to assess the Effectiveness of Pomegranate Popsicles on Inflammation of the oral mucosa among Patients on Chemotherapy in a Selected Hospital at Chennai.

1.3 OBJECTIVES OF THE STUDY

- To evaluate the effectiveness of pomegranate popsicles on oral mucositis among patients receiving chemotherapy in experimental and control group.

- To find out the association between the post-test level of oral mucositis among patients receiving chemotherapy with their selected demographic variables.

1.4 OPERATIONAL DEFINITIONS

Effectiveness: Refers to the reduction in the occurrence or absence of oral mucositis as assessed by using W.H.O scale for assessing oral mucositis after the administration of Pomegranate Popsicles.".

Pomegranate Popsicles: Refers to the fresh frozen pomegranate (Punica granatum – Ruby variety) juice cubes with a length 4cm, width 2.5cm, height 3cm, surface area 59cm^2, volume 30cm^3 equivalent to 10ml with smooth corners and a 7cm ice-cream stick to hold.

Inflammation of the oral mucosa: Refers to the soreness or erythema of oral mucosa occurring as a side effect of chemotherapy which can be assessed using W.H.O scale for assessing mucositis scale.

Patient: Refers to both male and female subjects in the age group of 30-60 years, who being diagnosed with cancer (excluding oral cancer), and are undergoing first cycle chemotherapy.

Chemotherapy: Refers to the use of drug therapy with drugs like (etoposide, platinol, mitomycin and vinblastin) to treat patients diagnosed with cancer.

1.5 RESEARCH HYPOTHESIS

H_1: There is a significant difference in the post-test levels of inflammation on the oral mucosa among patients on chemotherapy between experimental and control group.

H_2: There is a significant association between the post-test levels of inflammation of the oral mucosa among patients on chemotherapy with their selected demographic variables.

1.6 ASSUMPTIONS

1) The patients receiving chemotherapy may develop inflammation of the oral mucosa as its side effect.

2) Using Pomegranate Popsicles application is non pharmacological measure of preventing inflammation of the oral mucosa among patients on chemotherapy.

3) Oral cooling reduces the distribution of the chemotherapeutic agents to the oral mucosa by causing vasoconstriction.

1.7 DELIMITATIONS

1) Study limited for 4 weeks

2) Limited to only patients on first cycle chemotherapy.

CHAPTER – II
2.1 REVIEW OF LITERATURE

Reviewing of literature was an essential component of the research study as it provides a broad understanding of the research problem. A review of related literature involves the systemic identification, location scrutiny and summary of written materials that contain information on research problems (Polit and Hungler 1998). Keeping this in mind the investigator probed into the accessible sources and gained in depth understanding from the related studies. It gives a theoretical base for the research and helps to determine the nature of research.

Literature relevant to the present study was mentioned under the following headings:

PART – I: LITERATURE RELATED TO

1) Studies related to oral mucositis as a side effect of cancer.

2) Studies related to the prevention of oral mucositis by cryotherapy condition.

3) Studies related to pomegranate and its effect on cancer.

1. Studies related to oral mucositis as a side effect of cancer.

Cheng KK et al (2012) A multicenter study was conducted to characterize the range of oral symptoms and affect upon quality of life reported by patients in relation to the severity of oral mucositis and symptom burden during chemotherapy. The study included a total of 140 patients undergoing chemotherapy. Participants completed the self-report Mouth and Throat Soreness-related Questions of the Oral

Mucositis Daily Questionnaire (OMDQ) for 14 days and the Oral Mucositis-specific Quality of Life Measure (OMQoL) at baseline, day 7, and day 14. The incidences of non-severe and severe mucositis were 23% (n = 32) and 18% (n = 25), respectively. The symptoms reported by the patients with oral mucositis were related to eating (82.4%), swallowing (78.9%), drinking (75.4%), sleeping (71.9%), and talking (43.9%). Approximately 39% (22 out of 57) of patients with mucositis reported at least two simultaneous symptoms resulting from oral mucositis. About a quarter of them (25%, 14 out of 57) reported having all five symptoms concurrently. The study concluded that severe oral mucositis is a common cause of morbidity in patients undergoing chemotherapy. High-symptom burden due to oral mucositis may have profound impacts on patient quality of life and levels of psychological distress.

Naima Otmani et al (2011) A prospective study was conducted to analyse the incidence and to determine the severity of oral mucositis (OM) in cancer patients. Patients with malignant disease treated by chemotherapy between January 2001 and December 2006 were recorded. Patients (n = 970) with malignant disease were studied. The result showed that OM occurred in 540 (55.6%) patients, and 17.9% of them encountered severe grades. Mean time of onset of the lesions was 10.5 ± 6.8 (range, 1-22 days) and mean duration was 6.8 ± 3.1 (range, 2-23 days). The study concluded that underlying disease and chemotherapy regimens are the principal risk factors of OM development.

Raber-Durlacher JE et al (2010) A study was conducted to assess the Oral mucosal damage which is the side effect of radiotherapy and chemotherapy treatment for cancer. The samples of 60 patients were

selected. Oral mucositis prevalence, risk factors, clinical and economic impacts, etiology, and clinical management in view of the most recent evidence. With prevalence between 10% and 100%, depending on the cytotoxic and/or radiotherapy regimen and patient-associated variables, this morbid condition represents a significant problem in oncology. The result of the study was despitly clear progress and the development of clinical guidelines on this topic, what currently have to offer to patients to manage mucositis and oropharyngeal pain is still inadequate. The study concluded that Expansion of the knowledge of the pathogenesis of mucositis as well as a better insight into individual risk factors will provide opportunities to improve management strategies.

Linda S Elting et al (2008) A prospective study was conducted to assess the demonstration of the frequency, severity, resistance to palliation and impact on quality of life of adolescent patients. A sample of 126 patients with head and neck cancer were prospectively estimated. A validated, patient-reported questionnaire on oral mucositis daily questionnaire, quality of life (QOL), and the Functional Assessment of Chronic Illness Therapy (FACIT) and fatigue scales were used to measure mucositis (reported as mouth and throat soreness), daily functioning, and use of analgesics. The study showed that risk of mucositis was virtually identical in the 126 patients with oral cavity or oropharynx tumors (99% overall; 85% grade 3-4) compared with 65 patients with tumors of the larynx or hypo pharynx (98% overall; 77% grade 3-4). The mean QOL score decreased significantly during RT, from 85.1% at baseline to 69.0% at sixth week, corresponding with the peak of mucositis severity. The study concluded that Mucositis occurs virtually among all patients who are undergoing radiation treatment with chemotherapy for head and neck cancers. The detrimental effects on

QOL and functional status are significant, and opioid analgesia provides inadequate relief.

Karen L. Syrjala et al (2004) A study is to estimate the impact of oral mucositis and its sequelae on health-related quality of life (HRQOL) and develop a daily diary measure of mucositis-related HRQOL in patients receiving mucotoxic cancer therapy. Two focus groups were conducted with patients who were suffering or had suffered from mucositis as a result of mucotoxic cancer therapy. Forty-seven patients receiving hematopoietic stem cell transplantation or treatment for stage III or IV colorectal cancer or head and neck cancer completed the daily diary questionnaire, along with other ratings of functional activity. The study concluded that Oral mucositis afflicts 40%–70% of patients who receive conventional chemotherapy or radiation treatment. Hematopoietic stem cell transplant recipients have a mucositis rate of over 90%. Despite the frequency of severe oral mucositis in these patients, little attention has been given to its effects on their functioning and well-being or HRQOL

2. Studies related to the prevention of oral mucositis by cryotherapy.

Roham Salek (2012) A randomized controlled trial assessing the effect of oral cryotherapy on the incidence and severity of chemotherapy-induced oral mucositis in combined chemotherapy regimens in 80 cancer patients. Patients were divided into two groups, experimental and control. The experimental group was given ice to place in their mouths from 5 min before to 5 min after chemotherapy. The control group received no intervention. According to the WHO based Oral Mucositis Scale, the incidence of oral mucositis in the intervention group (45%) was significantly lower than the control group (77.5%;

P=0.01). The incidence of oral mucositis in the intervention group based on the Patient-Judged Oral Mucositis Scale was lower than the control group. The findings of this study indicated that patients who underwent cryotherapy had less severe oral mucositis based on both WHO (P=0.01) and patient oral mucositis scales (P=0.001). The study concluded that, oral cryotherapy because of its ease of application, tolerability and lack of side effects makes it an important resource for reducing the incidence and severity of oral mucositis.

Katranci, N et al (2012) A randomized controlled trial with random assignments to the experimental and control groups, was conducted with cancer patients. The study included 60 patients; 30 patients in the study group were instructed to hold ice cubes in their mouth shortly before, during, and shortly after infusion of 5-FU with leucovorin, the 30 patients in the control group received routine care. Oral mucositis in the patients was evaluated at 7, 14, and 21 days after chemotherapy. For analysis of data, chi-square, Fisher's tests were used; $p < 0.05$ was accepted as statistically significant. In the majority of patients receiving cryotherapy, oral mucositis was not observed (Grade 0) at 7 and 14 days. Similarly, incidence of Grades 1, 2, and 3 oral mucositis in the experimental group was quite a bit lower when compared to the control group ($p < 0.05$). On day 21, no statistically significant difference between the experimental and control groups was determined based on the development of oral mucositis ($p > 0.05$). Its found that oral cryotherapy has a significant contribution to the protection of oral health by reducing mucositis score according to the WHO mucositis scale, especially on the 7th and 14th days. Nurses' awareness of how cryotherapy can affect patients and options for resolving problems will enable them to provide a higher standard of individualized care.

Castelino Flavia, Devi Elsa Sanatombi, Jyothi R K, (2011) A study focusing on prevention of mucositis among cancer patients receiving chemotherapy using plain versus flavored ice cubes to care their pain and improve their quality of life with fewer complications. The objectives of the study were to assess the oral mucosa before and after the treatment, to identify the experiences of patients during the therapy while sucking the ice cubes and compare the effectiveness of plain ice cubes versus flavored ice cubes in preventing oral mucositis. An experimental approach with Cross- over Design was adopted to identify the difference in the effectiveness of the treatments in both the groups. The maximum (14) number (66.9%) of patients were in the age group of 34–65 years, thirteen (59.1%) were males, all 22 (100%) of them were suffering with cancer of the Gastro Intestinal tract. The majority 15 (68.2%) have received injection 5-FU with Leucovorin, Twenty (91%) were diagnosed to have cancer since 1–12 month duration, and Nineteen (86.4%) of them were operated once. The check list scores of the patients showed that there is a difference in the experiences of the patients while sucking plain ice cubes and flavored ice cubes. As a whole the results showed that the flavored ice cubes were effective in preventing mucositis and the patients were in favor of the flavored ice cubes.

Svanberg A et al (2010) A study to investigate if oral cryotherapy during myeloablative therapy may influence frequency and severity of mucositis. A stratified randomisation was used. Mucositis was measured on WHO mucositis scale. Number of days of total parenteral nutrition, infection rate, weight, albumin levels and days at hospital was compared. There were significantly fewer patients in the experimental group with mucositis grade 3-4 than in the control group and significantly lower number of days in the hospital. Less total

parenteral nutrition was needed in the experimental group in both settings, and the S-albumin level was significantly better preserved. No significant difference could be found with regard to infection rate. The study concluded oral cryotherapy reduced mucositis, number of hospital days, the need for total parenteral nutrition and resulted in a better nutritional status.

Prescrire INT (2008) An experimental study was conducted to assess effectiveness orodental hygiene and the ice cubes in patients undergoing chemotherapy. Samples of 200 patients were randomized to suck ice chips during chemotherapy. The result showed that sucking ice during chemotherapy reduced the incidence of severe oral mucositis, from 14-74% to 4-21%. Analgesics especially morphine should be used to treat intense pain. Local anesthetics have not been tested in patients with damaged oral mucosa, but they can cause a burning sensation and carry a risk of swallowing disorders due to anesthesia of the oropharyngeal junction .The study concluded that In practice, prevention of oral mucositis due to cancer chemotherapy or radiotherapy is based on orodental care and ice rather than drugs.

Papadeas E et al (2007) A prospective randomized study investigating whether oral cryotherapy alleviates chemotherapy induced oral mucositis. Thirty six patients, included in the cryotherapy group, were instructed to hold ice cubes in their oral cavity, shortly before, during and shortly after the infusion of chemotherapy. Both mean physician and patient-graded stomatitis of our cryotherapy group were compared with those of a control group (40 patients) and were found significantly reduced for all three chemotherapy cycles. The percentage of patients who were free from oral toxicity was significantly higher in the cryotherapy group in all three chemotherapy cycles, as judged both

by patients and physicians oral mucositis scale. The results of this study encourage the use of cryotherapy in patients receiving chemotherapy in alleviating oral mucositis by using a side-effect-free, easy to perform and inexpensive measure, which does not interfere with the efficacy of antineoplastic agents.

Lilleby K et al (2006) A prospective, randomized study of cryotherapy during administration of chemotherapy. Forty patients with multiple myeloma scheduled to receive chemotherapy were randomly assigned to receive oral cryotherapy or room temperature normal saline rinses 30 min before and after the chemotherapy. Patients were evaluated for the development of mucositis using the National Cancer Institute grading system as well as evaluation of secondary measures such as days of total parenteral nutrition (TPN), narcotic use, hospitalization, weight loss and resumption of oral caloric intake. Patients self-scored their pain, swallowing, drinking, eating, sleeping and taste alterations. The primary end point of this trial was the incidence of grades 3-4 mucositis. Compared to the normal saline group, patients using cryotherapy experienced less grade 3-4 mucositis, 14 vs 74%, P=0.0005. Patients receiving cryotherapy also had statistically lower uses of narcotics and TPN, although there were no differences in length of hospitalization or weight loss. Patient-reported pain was significantly lower and activities were significantly better in the cryotherapy group.

Mustafa Baydar et al (2005) The study investigated the effects of local cryotherapy on oral mucositis incidence during administrated of chemotherapy. In a total of 99 courses, chemotherapy was given to 40 patients. Findings from the study showed that while mucositis developed in 6.7% of the courses given with cryotherapy, this ratio was 38.9% in

courses given without cryotherapy. In the logistic regression analysis, development of mucositis had been found to correlate only with cryotherapy. Odds ratio (OR) = 11.5; in the 95% confidence interval (CI) = 3.2 - 41.9; (p = 0.001). The study concluded that the effects of cryotherapy in preventing oral mucositis due chemotherapy regimens were promising.

Karagözoğlu S, Filiz Ulusoy M. (2005) The aim of the study was to investigate the effect of oral cryotherapy on the development of chemotherapy-induced mucositis in patients administered combined chemotherapy. Study involved 60 patients, 30 of whom were in the study group and 30 in the control group. Ice cubes at a size that can be moved easily in the mouth and whose corners have been smoothed in order that they will not cause irritation in the mouth has been used in oral cryotherapy in the study group. Oral chemotherapy was initiated five minutes before chemotherapy and maintained during venous infusions of etoposide (Vepesid), platinol (Cisplatin), mitomycin (Mitomycin-C) and vinblastin (Velbe) depending on the chemotherapy course. According to Patient-Judged Mucositis Grading, the rate of mucositis is 36.7% in study group and 90.0% in control group, the difference between two groups being statistically significant ($P < 0.05$). According to Physician-Judged Mucositis Grading, the rate of mucositis is 10.0% in the study group and 50.0% in the control group, the difference between two groups being statistically significant ($P < 0.05$). Oral pH values decreased in 90% of the subjects in study group, i.e. mucositis risk was reduced. The findings have demonstrated that oral cryotherapy makes an important contribution to the protection of oral health by reducing the mucositis score according to patient- and physician-judged mucositis score and by increasing oral pH values.

Nikoletti S et al (2005) The study aimed to compare the use of plain ice, flavoured ice and standard care, to evaluate the effect on mucositis and to determine patients' perceptions of the two forms of oral cryotherapy. Patients were randomized to receive each of three interventions across three cycles of chemotherapy: standard care alone; standard care plus plain ice; and standard care plus flavoured ice. Oral mucositis was assessed by nurses prior to each of the three chemotherapy cycles and 15 days after each intervention. Two assessment tools were used, the Oral Assessment Guide, and the Western Consortium Cancer Nursing Research Scale. Findings from 67 patients revealed that when participants used standard care alone, they were significantly more likely to experience symptoms of mucositis than when they used either plain or flavoured ice.

3***. Studies related to pomegranet and its effect on cancer*.**

Wang L et al. (2014) Prostate cancer is the second leading cause of cancer deaths in men in the United States. There is a major need for less toxic but yet effective therapies to treat prostate cancer. Pomegranate fruit from the tree Punica granatum has been used for centuries for medicinal purposes and is described as "nature's power fruit". Recent research has shown that pomegranate juice (PJ) and/or pomegranate extracts (PE) significantly inhibit the growth of prostate cancer cells in culture. In preclinical murine models, PJ and/or PE inhibit growth and angiogenesis of prostate tumors. More recently, we have shown that three components of PJ, luteolin, ellagic acid and punicic acid together, have similar inhibitory effects on prostate cancer growth, angiogenesis and metastasis. Results from clinical trials are also promising. PJ and/or PE significantly prolonged the prostate specific antigen (PSA) doubling time in patients with prostate cancer.

Viladomiu M et al (2013) Pomegranate fruit presents strong anti-inflammatory, antioxidant, antiobesity, and antitumoral properties, thus leading to an increased popularity as a functional food and nutraceutical source since ancient times. It can be divided into three parts: seeds, peel, and juice, all of which seem to have medicinal benefits. Several studies investigate its bioactive components as a means to associate them with a specific beneficial effect and develop future products and therapeutic applications. Many beneficial effects are related to the presence of ellagic acid, ellagitannins (polyphenol formed from ellagic acid and anti-viral properties), punicic acid (anti-inflammatory), flavonoids (antioxidant), estrogenic flavonols (antioxidant and anti-inflammatory), and flavones which seem to be its most therapeutically beneficial components. However, the synergistic action of the pomegranate constituents appears to be superior when compared to individual constituents. Promising results have been obtained for the treatment of certain diseases including obesity, insulin resistance, intestinal inflammation, and cancer. To summarize there is a potential health effects and mechanisms of action of pomegranate extracts in inflammatory diseases.

Ismail T, Sestili P, Akhtar S. (2012) An extensive and systematic review of the extant literature was carried out, and the data under various sections were identified by using a computerized bibliographic search via PubMed, Web of Science and Google Scholar. All abstracts and full-text articles were examined. The most relevant articles were selected for screening and inclusion in this review. A variety of pomegranate ethnomedical uses have been recorded. Additionally, over the last decade, there has been a dramatic increase of interest in pomegranate as a medicinal and nutritional product due to its n1ewly identified potential health effects, which include treatment and

prevention of cancer and cardiovascular diseases. From the toxicological perspective, pomegranate fruit juice, extracts and preparations have been proven to be safe.

Rocha A, Wang L, Penichet M (2012) Breast cancer is the most common cancer and the second leading cause of cancer death and morbidity among women in the western world. Pomegranate juice (PJ) and three of its specific components have been shown to inhibit processes involved in prostate cancer metastasis. If this also proves to be true for breast cancer, these natural treatments will be promising agents against breast cancer that can serve as potentially effective and nontoxic alternatives or adjuncts to the use of conventional selective estrogen receptor modulators for breast cancer prevention and treatment. To test this possibility, we have used two breast cancer cell lines, MDA-MB-231 cells (ER(-)) and MCF7 (ER(+)), and the non-neoplastic cell line MCF10A. We show that, in addition to inhibiting growth of the breast cancer cells, PJ or a combination of its components luteolin (L) + ellagic acid (E) + punicic acid (P) increase cancer cell adhesion and decrease cancer cell migration but do not affect normal cells.

Khan SA (2009) Colon cancer is one of the major causes of cancer-related death in the Western world. Although cytotoxic chemotherapeutic agents are available to treat the disease, these agents become ineffective as the disease advances to an invasive state. An alternative but viable approach to reduce the incidence of this deadly disease is then, to increase the dietary intake of relatively non-toxic fruits and vegetables. An example of a fruit with antioxidant, antidiabetic and anti-atherosclerotic properties is pomegranate. Pomegranate produces anticancer effects in experimental models of

lung, prostate and skin cancer. More recently, pomegranate has been found to be anti-carcinogenic in the colon.

2.2 CONCEPTUAL FRAMEWORK

Conceptual framework refers to framework of prepositions for conducting research. Conceptual framework serves as a spring board for theory development. As this made up of concepts which are mental images of a phenomenon.

The conceptual framework setup for the study is Model of Widenbach's helping art of clinical nursing theory. Ernestine Wiedenbach proposed a prescriptive theory of nursing which is described as a conceiving of a desired situation and the ways to attain it. Prescriptive theory directs action towards an explicit goal. It consists of three factors: Central purpose, Prescription and realities. A nurse develops a prescription based on a central purpose and implements it according to the realities of the situation.

THE MAIN CONCEPTS OF WIDENBACH'S HELPING ART OF CLINICAL NURSING THEORY ARE

- Central purpose in the model refers to what the nurse wants to accomplish. It is the overall goal towards which a nurse strives: it transcends the immediate intent of the assignment or task by specifically directing activities towards the patients goal.

- Prescription refers to the plan of care of the patient .It specifies the nature of the action that will fulfil the nurse‟s central purpose and the rationale for the action.

- Realities refer to physical, psychological, emotional and spiritual factors that come in to play in a situation involving nursing actions. The five realities identified by wiedenbach are agent, recipient, goal, means and framework, where the agent is the nurses desired outcome, the means are the activities and devices used by the nurse to achieve goal, and the frame work refers to the facilities in which nursing practiced.

- Wiendenbach views nursing practice closely parallels the assessment, implementation and evaluation.

STEPS OF THE NURSING PROCESS

According to Wiedenbach nursing practice consists of

- Identifying need for help
- Ministering needed for help
- Validating the need for help

Investigator has selected this model for assessing the effectiveness of Pomegranate Popsicles on inflammation of the oral mucosa among first cycle chemotherapy patients at Dr.Kamakshi Memorial Hospital Chennai. This models views that Pomegranate Popsicles has preventive effect on inflammation of the oral mucosa among first cycle chemotherapy patients. The central purpose of the study is to evaluate the effectiveness of Pomegranate Popsicles on inflammation of the oral mucosa among first cycle chemotherapy patients.

THE REALITIES IDENTIFIED IN THE STUDY ARE

Agent – Investigator.

Recipient - Chemotherapy patients who fulfill the inclusion criteria.

Goal – Prevention of inflammation on the oral mucosa among chemotherapy patients

Mean - Pomegranate Popsicles

Environment – Chemotherapy Department of Dr.Kamakshi Memorial Hospital at Chennai.

With the goal of improving the oral health among chemotherapy patients, the investigator as an agent conducted the study by ministering need for help through pomegranate popsicles application on oral mucosa there by preventing inflammation of oral mucosa. Chemotherapy patients are recipients of care. Dr.Kamakshi Memorial Hospital, Chennai is the selected environment. The pre-test level of the oral mucositis among chemotherapy patients were assessed using the WHO Oral Mucositis Scale. By validating the need for help the post test level of oral mucositis was assessed on seventh day after pomegranate popsicles application on oral mucosa. The effectiveness of the intervention (Pomegranate Popsicles) on oral mucosa has either positive outcome or negative outcome. The positive outcome reveals that pomegranate popsicles application effectively prevented the level of oral mucositis and hence the pomegranate popsicles application is effective. The negative outcome reveals that the intervention does not prevent the oral mucositis occurrence.

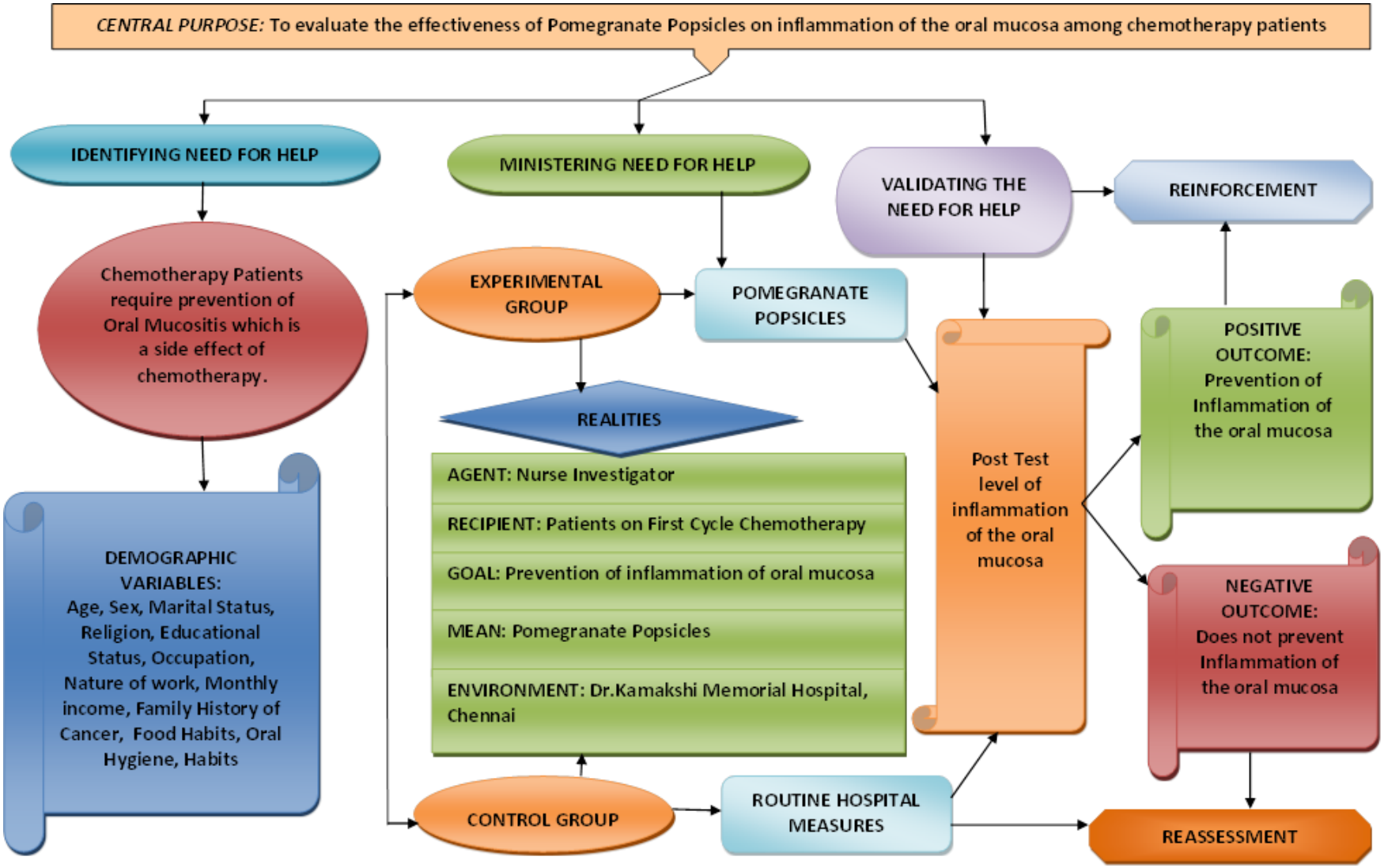


FIGURE 1: CONCEPTUAL FRAME WORK BASED ON WIEDENBACH'S HELPING ART OF CLINICAL NURSING THEORY (1969)

CHAPTER – III
RESEARCH METHODOLOGY

This chapter deals with the description of different steps which are taken by the investigator for the present study. It comprises of the research approach, research design, variables, research setting, population, sample and sample size, sampling technique, sampling criteria, development and description of tool, Validity and reliability of the tool, ethical considerations, pilot study, data collection procedure, and plan for statistical data analysis.

3.1 RESEARCH APPROACH

Research approach is an umbrella that covers the basic procedure for conducting research. The research approach adopted in this study is Quantitative Research approach in nature focusing on the effectiveness of Pomegranate Popsicles on Inflammation of the oral mucosa among chemotherapy patients.

3.2 RESEARCH DESIGN

The research design adopted for the present study is Quasi experimental post test only control group research design.

Group	Pre-Test	Intervention	Post-Test
Experimental Group	-	X	O_2
Control Group	-	-	O_2

Key:

O_1 – Pre test

X – Pomegranet Popsicles

O_2 – Post test

3.3 VARIABLES OF THE STUDY

Independent variable: Pomegranate Popsicles

Dependent variable: Inflammation of the oral mucosa

3.4 SETTING OF THE STUDY

Dr.Kamakshi Memorial Hospital a Super speciality hospital providing services to all the divisions of health care including cancer care, pioneered not only in advanced scientific management of diseases but also in equipping with modern technologically advanced Gadgets.

This hospital provides services to all the divisions of health care including advanced care with Chemotherapy, Brachytherapy & Radiotherapy for cancer patients. This well-established 150-bed multispecialty hospital caters to millions of people in and around the Chennai metropolitan area. The hospital also serves a number of patients from abroad. Their success rates are comparable to the best centers in the world. Committed to deliver scientific modern medical care to the society with International standards at an affordable cost, this hospital treats more than 2000 cancer patients per year.

3.5 POPULATION

The population of the study includes patients on chemotherapy in Dr. Kamakshi Memorial Hospital.

3.6 SAMPLES

The samples were 60 cancer patients on chemotherapy who fulfill inclusion criteria.

3.7 SAMPLE SIZE

Sample size is 60. (Experimental group 30, Control Group 30)

3.8 SAMPLE SELECTION CRITERIA

INCLUSION CRITERIA

Study includes: - Patients who are;

1. On the first cycle of chemotherapy.
2. Willing to participate at the time of the study.
3. Between 30 years to 60 years of age.

EXCLUSION CRITERIA

1. Patients who underwent oral surgery.
2. Patients who have oral Mucositis prior to chemotherapy.
3. Patients who have oral cancer.

3.9 SAMPLING TECHNIQUE

The subjects of the present study were selected by non probability, purposive sampling technique.

3.10 DEVELOPMENT OF THE TOOL

The tools were standardized – W.H.O - ORAL MUCOSITIS SCALE

3.11 DESCRIPTION OF THE TOOL

The tool consists of two parts: Part I and Part II

***Part I*:**

Demographic variable of the patients receiving chemotherapy such as age, sex, religion, education, occupation, food habits, oral hygiene.

Part II: W.H.O. Oral Mucositis Assessment Scale.

3.12 ETHICAL CONSIDERATION

The proposed study was conducted after the approval of the ethics committee of Venkateswara Nursing College, Thalambur, Chennai. Permission was obtained from Dr. Kamakshi Memorial Hospital, assurance was given to the patients that confidentiality of each patient will be maintained and written consent was obtained. The participants were informed that they are free to withdraw from the study at any time during the course of the study period if they wish.

3.13 TESTING OF THE TOOLS

The content validity of the tool was established on the basis of opinion from five experts.

3.13.1 CONTENT VALIDITY

In order to determine the content validity, the tool was submitted to Nursing Experts in the specialty of Medical Surgical Nursing, a Medical Expert who is a Surgical Oncologist and a Statistician who is a Research Officer and their suggestions were incorporated in the tool. There was no ambiguity in language in the tool and the tool was found feasible.

3.13.2 RELIABILITY OF THE TOOL

In order to determine the Reliability of the tool test retest method was used and the tool was found to be reliable. The reliability of the tool was by test retest method found (r=0.8), and the tool was considered as fit for proceeding with pilot study.

3.13.3 PILOT STUDY

A pilot study was conducted to assess the feasibility and practicability of the tool and it also helped to determine the plan of data

analysis. Prior permission to conduct the study was obtained from the administration of Dr.Kamakshi Memorial Hospital on 6.9.14 to11.9.14 who fulfill the inclusion criteria were selected (experimental group-3, control group-3) by non probability purposive sampling technique. The purpose of the study was explained to subjects and a written consent was obtained from them. Confidentiality was assured to all the subjects. The demographic data was collected with the help of questionnaire. The tool used is a standardized WHO oral mucositis Scale. Data collected was analyzed using descriptive and inferential statistics. The results showed that there was significant difference among the post test levels of oral mucositis in experimental and control group, the tool was found feasible to proceed for the main study.

3.14 DATA COLLECTION PROCEDURE

The main study was conducted in Dr.Kamakshi Memorial Hospital Pvt.Ltd., Radial Road, Pallikaranai, Chennai, after obtaining permission from the concerned hospital authority. Purposive sampling technique was used to select 30 samples into experimental group and 30 patients into control group based on inclusion criteria. The study lasted for a period of 4 weeks during which, the first and second weeks subjects were taken as experimental group and in the third and fourth weeks subjects were taken as control group.

Phase -1 Demographic data was collected from the subjects using a questionnaire.

Phase-2: Intervention with pomegranate popsicles was given to subjects in the experimental group on the same day. Pomegranate Popsicles was given to patients 5 minutes prior to, maintained 5 minutes during infusion and 5 minutes after infusion of chemotherapeutic agent. The

subjects were asked to keep the popsicles inside the mouth in contact with the inner cheek wall of the oral cavity, the right side first and then on the left side, thereby cooling the oral cavity. The subjects in the control group followed the routine standard care of mouth wash with fresh water three times a day.

Phase-3 Post test level or oral mucositis was assessed on the seventh day using the W.H.O Oral Mucositis Scale. The data was then organized for statistical analysis.

3.15 DATA ANALYSIS PROCEDURE

Data collected analysed by using descriptive and inferential statistics on the basis of objectives and inferential statistics on the basis of the objectives and hypotheses of the study.

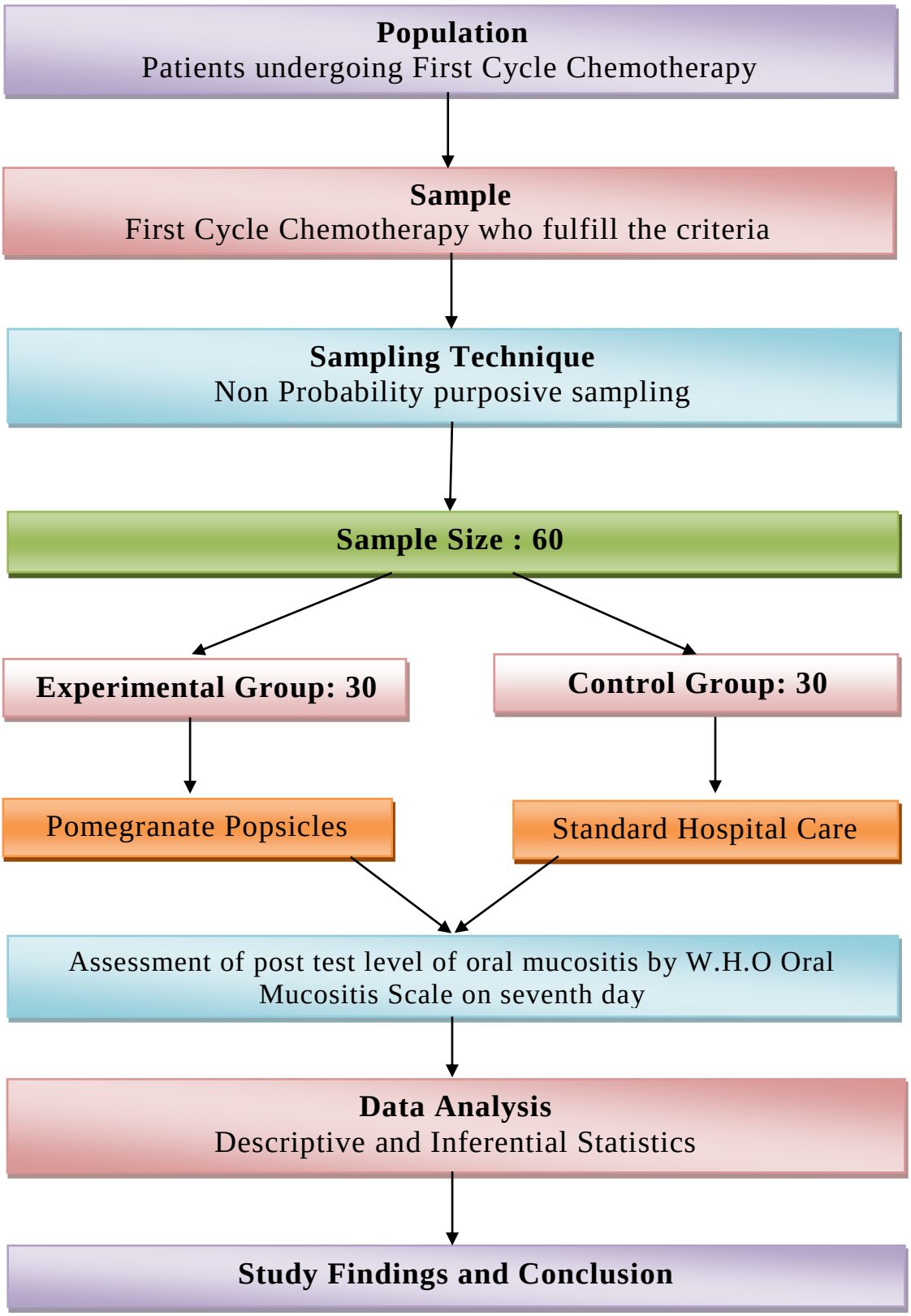
DESCRIPTIVE STATISTICS

- Frequency, percentage distribution, will be used to describe demographic variables.
- Mean and standard deviation will be used to assess the level of oral mucositis in patient undergoing chemotherapy.

INFERENTIAL STATISTICS

- Paired t test will be used to compare the post-tests mean score level of inflammation of the oral mucosa among patients on chemotherapy in experimental and control group.
- Chi- square test will be used to find the association between the post-tests mean score level of inflammation of the oral mucosa among patients on chemotherapy and their selected demographic variables.

FIGURE 2: SCHEMATIC REPRESENTATION OF STUDY DESIGN



CHAPTER – IV
DATA ANALYSIS AND INTERPRETATION

Processing the data implies coding, classification and tabulation of collected data that they are amenable to analysis.

Analysis is defined as categorizing, ordering, manipulating, and summarizing of data to reduce to intelligible and interpretable form, so that research problems can be studied and tested with relationship between the variables – ***(Polit and Hungler, 2008).***

The chapter deals with the analysis and interpretation of data. Data collected from 60 patients on first cycle chemotherapy were analyzed to assess the effectiveness of Pomegranate Popsicles on inflammation of the oral mucosa among chemotherapy Patients and tabulated according to the plan for data analysis and are interpreted according to the following headings:

ORGANIZATION OF DATA

The data obtained from samples of 60 patients were analysed and presented in this chapter under the following headings:

Section-I Distribution of subjects according to their selected demographic variables.

Section-II Comparison of the post-test level of oral mucositis among experimental and control group.

Section-III Effectiveness of pomegranet popsicles on the level of oral mucositis among experimental and control group.

Section-IV Association in the level oral mucositis among experimental and control group with the selected demographic variables.

SECTION I-A: DISTRIBUTION OF SUBJECTS ACCORDING TO THEIR SELECTED DEMOGRAPHIC VARIABLES.

Table – 4.1: Frequency and Percentage Distribution of Subjects According to Demographic Variables

N = 60

S.No	Demographic variables	Experimental Group (n=30)		Control Group (n=30)	
		f	%	f	%
1.	**Age (in years)**				
	a) 30-39	3	10.0	4	13.3
	b) 40-49	7	23.3	7	23.3
	c) 50-60	20	66.7	19	63.3
2.	**Sex**				
	a) Male	9	30.0	8	26.7
	b) Female	21	70.0	22	73.3
3.	**Marital Status**				
	a) Married	26	86.7	26	86.7
	b) Unmarried	-	-	-	-
	c) Widower	4	13.3	4	13.3
	d) Divorced	-	-	-	-
4.	**Religion**				
	a) Hindu	25	83.3	28	93.3
	b) Muslim	2	6.7	1	3.3
	c) Christian	3	10.0	1	3.3
	d) Others	-	-	-	-

5.	**Educational Status**				
	a) Un Educated	-	-	-	-
	b) Primary School	3	10.0	2	6.7
	c) High School	11	36.7	14	46.7
	d) Graduate	16	53.3	14	46.7
6.	**Occupation**				
	a) Home Maker	18	60.0	22	73.3
	b) Government	-	-	-	-
	c) Private	9	30.0	4	13.3
	d) Business	3	10.0	4	13.3
7.	**Type of Activity**				
	a) Sedentary	7	23.3	2	6.7
	b) Moderate	22	73.3	28	93.3
	c) Heavy	1	3.3	-	-
8.	**Monthly Income**				
	a) < Rs.8000/-	-	-	-	-
	b) Rs.8001–10000/-	-	-	-	-
	c) Rs.10001–15000/-	-	-	-	-
	d) > Rs.15001/-	30	100	30	100
9.	**Family History of Cancer**				
	a) Yes	7	23.3	4	13.3
	b) No	23	76.7	26	86.7
10.	**Family History of Chemotherapy**				
	a) Yes	5	16.7	4	13.3
	b) No	25	83.3	26	86.7

This table describes the frequency and percentage distribution of samples according to demographic variables.

In regard to age, out of 60 samples, 3 (10%) of them were found to be the age group between 30 and 39 years, the age of 7 (23.3%) in the age group between 40 and 49 years, 20 (66.6%) in the age group between 50 and 60 years. Considering the control group, the age of patients undergoing chemotherapy 4 (13.3%) of them were found to be the age group between 30 and 39 years, the age of 7 (23.3%) in the age group between 40 and 49 Years, 19 (63.3%)in the age group between 50 and 60 years.

Regarding sex; 9 (30 %) are male patients and 21 (70 %) are female patients in experimental group; in control group 8 (26.7%) of them were male and 22 (73.3%) of them were females. Regarding marital status, 26 (86.7%) are married; 4 (13.3%) are widow; considering the control group 26 (86.7%) are married; 4 (13.3%) are widow.

Considering Religion; in experimental group 25 (83.3%) are Hindu; 2 (6.7%) are Muslim; 3 (10%) are Christian; in control group, 28 (93.3%) are Hindu; 1 (3.3%) is Muslim; 1 (3.3%) is Christian. Considering Educational status, in experimental group 3 (10%) are Primary School; 11 (36.7%) are High School; 16 (53.3%) are Graduate; In control group 2 (6.7%) are Primary School; 14 (46.7%) are High School; 14 (46.7 %) are Graduate.

With respect to occupation; in experimental group, 18 (60%) patients are Home Makers; 9 (30%) patients are Private sector workers; 3 (10%) patients are doing Business; In control group 22 (73.3%) patients are Home Makers; 4 (13.3%) patients are Private sector workers and 4 (13.3%) patients are doing Business.

Regarding the type of activity; in experimental group, 7 (23.3%) patients are Sedentary Workers; 22 (73.3%) patients are Moderate Workers; 1 (3.3%) patient is a Heavy Workers; in control group 2 (6.7%) patients are Sedentary Workers and 28 (93.3%) patients are Moderate Workers. Considering the Monthly Family income in experimental group and control group all patients have a family monthly income above >15000/-.

Considering the Family History of Cancer; in experimental group 7 (23.3%) of patients have a family history of cancer and 23 (76.7%) do not have a family history of cancer; considering the control group 4 (13.3%) have family history of cancer and 26 (86.7%) do not have a family history of cancer. Considering the Family History of Chemotherapy; in experimental group, 5 (16.7%) patients have a relative undergoing chemotherapy; 25 (83.3%) patients do not have relatives undergoing chemotherapy. In control group 4 (13.3%) patient has a relative undergoing chemotherapy and 26 (86.7%) patients do not have relatives undergoing chemotherapy.

SECTION I-B: ASSESSMENT OF DEMOGRAPHIC VARIABLES OF PATIENTS UNDERGOING CHEMOTHERAPY IN EXPERIMENTAL AND CONTROL GROUP WITH RESPECT TO ORAL HYGIENE

Table – 4.2: Frequency and percentage distribution of demographic variables in experimental and control group with respect to oral hygiene **N=60**

S.No	Demographic variables	Experimental Group (n=30)		Control Group (n=30)	
		f	%	f	%
1	**Mouth Wash**				
	a) Yes	6	20.0	3	10.0
	b) No	24	80.0	27	90.0
2	**Frequency of Brushing per day**				
	a) None	-	-	-	-
	b) Once	4	13.3	7	23.3
	c) Twice	26	86.7	23	76.7
	d) Thrice	-	-	-	-
3	**Item used for brushing**				
	a) Tooth Powder	-	-	-	-
	b) Toothpaste	29	96.7	27	90.0
	c) Charcoal Powder	1	3.3	3	10.0
	d) Chewing Stick	-	-	-	-
4	**Frequency of Gargle per day**				
	a) None	9	30.0	13	43.3
	b) Once	4	13.3	8	26.7
	c) Twice	16	53.3	8	26.7
	d) Thrice	1	3.3	1	3.3

Table 4.2 shows concerning **Oral Hygiene**, 5 (16.6%) patients in the experimental group use mouth wash solution; 25 (83.3%) patients do not use mouth wash solution. In control group 2 (6.6%) patients use mouth wash solution and 28 (93.3%) patients do not use mouth wash solution.

Regarding brushing habits, 4 (13.3%) patients in the experimental group brush once a day; 26 (86.6%) patients brush twice a day. In control group 7 (23.3%) patients brush once a day and 23 (76.6%) brush twice a day.

In experimental group 29 (96.6%) patients use toothpaste; 1 (3.3%) patient uses charcoal powder and in control group 30 (100%) patients use only toothpaste.

In experimental group 9 (30%) patients do not have the habit of gargling, 4 (13.3%) gargle once a day, 16 (53.3%) gargle twice a day and 1 (3.3%) patient gargles thrice a day. In control group 13 (43.3%) patients do not gargle, 8 (26.6%) gargle once a day, 8 (26.6%) gargle twice a day and 1 (3.3%) patient gargles thrice a day.

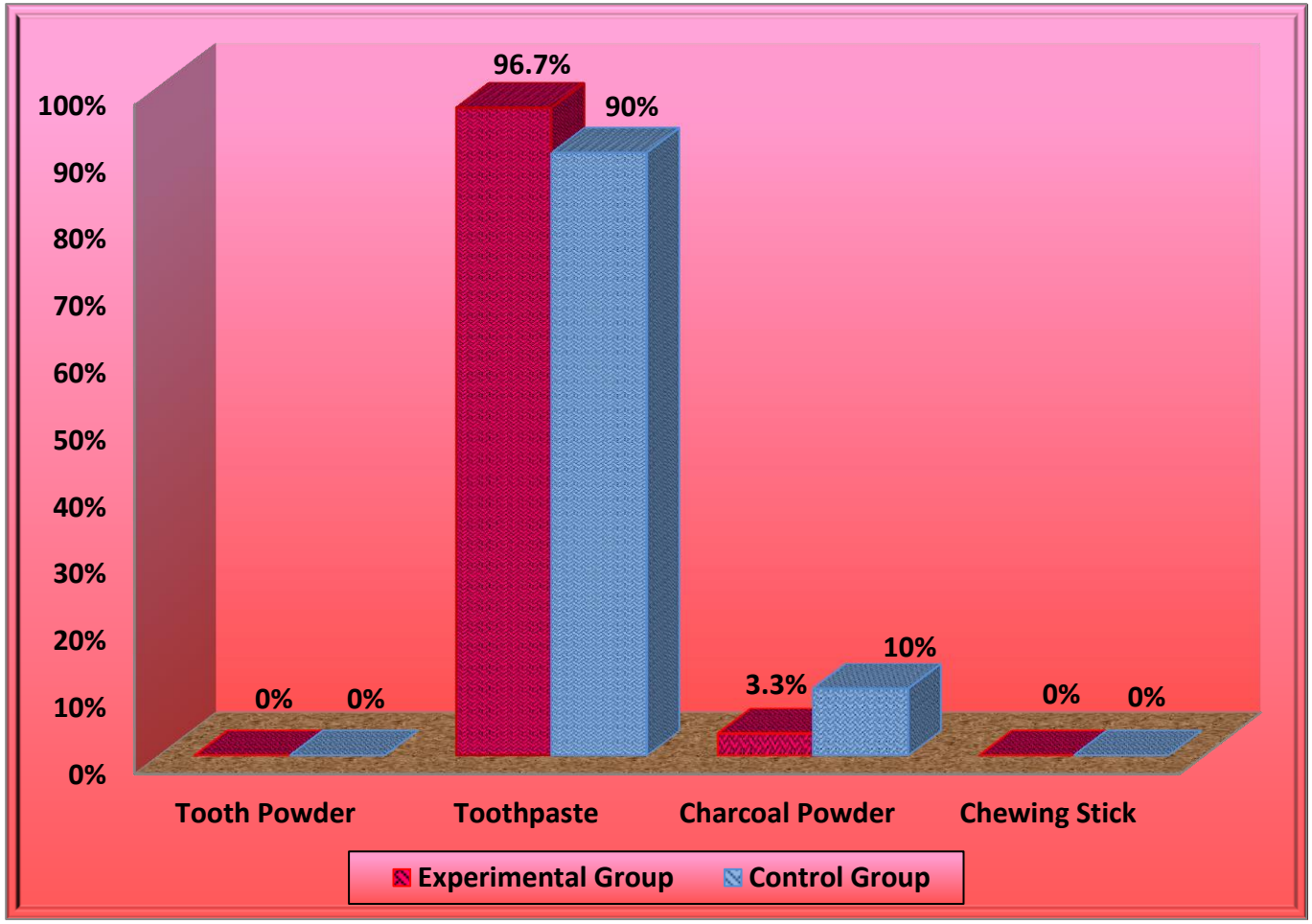


FIGURE 3: PERCENTAGE DISTRIBUTION OF SAMPLES ACCORDING TO ITEM USED FOR BRUSHING

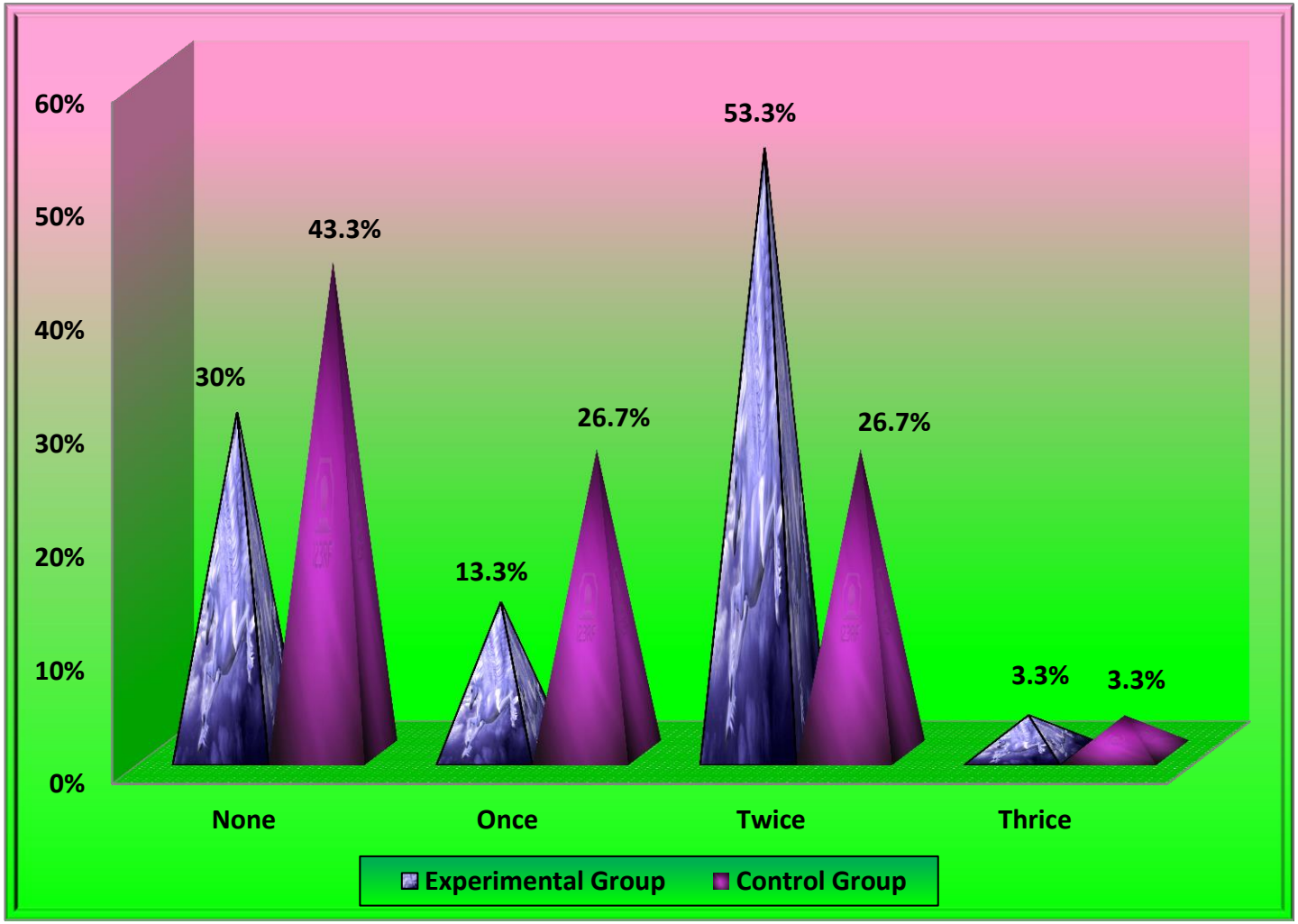


FIGURE 4: PERCENTAGE DISTRIBUTION ACCORDING TO FREQUENCY OF GARGLE PER DAY

SECTION I-C: ASSESSMENT OF DEMOGRAPHIC VARIABLES OF PATIENTS UNDERGOING CHEMOTHERAPY IN EXPERIMENTAL AND CONTROL GROUP WITH RESPECT TO DIET

Table 4.3: Frequency and percentage distribution of demographic variables of patients undergoing chemotherapy in experimental and control group with respect to diet.

(N=60)

Demographic variables	Experimental Group (n=30)		Control Group (n=30)	
	f	%	f	%
Dietary Pattern				
a) Vegetarian	9	30.0%	6	20.0%
b) Non Vegetarian	21	70.0%	24	80.0%
Eating Sweets				
a) Never	8	26.7%	6	20.0%
b) Everyday	-	-	-	-
c) Few times a week	14	46.7%	10	33.3%
d) Few times a month	8	26.7%	14	46.7%
Chat items in diet				
a) Never	7	23.3%	1	3.3%
b) Everyday	-	-	1	3.3%
c) Few times a week	15	50.0%	26	86.7%
d) Few times a month	8	26.7%	2	6.7%
Fizzy Drinks				
a) Never	22	73.3%	20	66.7%
b) Everyday	-	-	-	-
c) Few times a week	5	16.7%	4	13.3%
d) Few times a month	3	10.0%	6	20.0%

This table 4.3 presents regarding **Dietary Pattern** in experimental group 9 (30%) patients are vegetarian and 21 (70%) are Non Vegetarian. In control group 6 (20%) patients are vegetarian and 24 (80%) are Non Vegetarian.

In experimental group 8 (26.6%) patients never eat sweets; 14 (46.6%) patients eat sweets few times a week; 8 (26.6%) eat sweets only few times a month. In the control group 6 (20%) patients never eat sweets; 10 (33.3%) eat sweets few times a week and 14 (46.6%) eat sweets only few times a month.

In experimental group 7 (23.3%) patients never eat chat items; 15 (50%) patients eat chat items few times a week; 8 (26.6%) eat chat items only few times a month. In the control group 1 (3.3%) patient never eats chat items; 26 (86.6%) eat chat items few times a week and 2 (6.6%) eat chat items only few times a month.

In experimental group 22 (73.3%) patients never drink fizzy drinks; 5 (16.6%) patients drink fizzy drinks few times a week; 3 (10%) eat drink fizzy drinks only few times a month. In the control group 20 (66.6%) patient never drink fizzy drinks; 4 (13.3%) drink fizzy drinks few times a week and 6 (20%) drink fizzy drinks only few times a month.

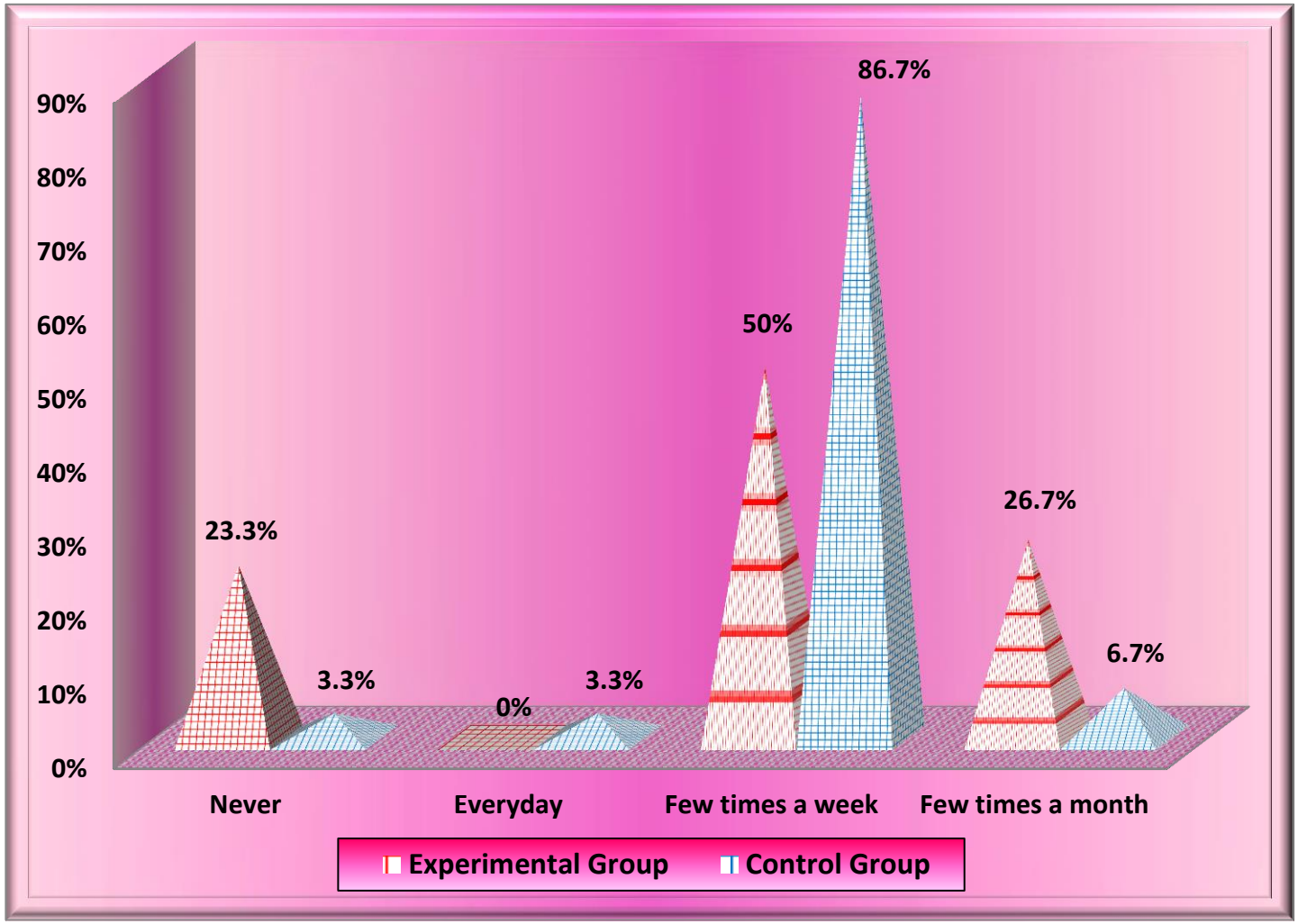


FIGURE 5: PERCENTAGE DISTRIBUTION OF SAMPLES ACCORDING FREQUENCY OF TAKING CHATS

SECTION I-D: ASSESSMENT OF DEMOGRAPHIC VARIABLES OF PATIENTS UNDERGOING CHEMOTHERAPY IN EXPERIMENTAL AND CONTROL GROUP WITH RESPECT TO HABITS

Table – 4.4: Frequency and Percentage Distribution of Samples According to Demographic Variables

N = 60

Demographic variables	Experimental Group (n=30)		Control Group (n=30)	
	f	%	f	%
Chewing Tobacco				
a) Yes	5	16.7	9	30.0
b) No	25	83.3	21	70.0
Smoking or Drinking Alcohol				
a) Yes	2	6.7	5	16.7
b) No	28	93.3	25	83.3

This table 4.4 shows regarding Habits; in experimental group 4 (13.3%) patients have the habit of chewing tobacco; whereas 26 (86.6%) patients do not chew tobacco. In control group, 3 (10%) patients chew tobacco and 27 (90%) patients do not chew tobacco.

In experimental group 2 (6.6%) patients have the habit of smoking or drinking and 28 (93.3%) do not have the habit of smoking or drinking alcohol. In control group also 2 (6.6%) patients have the habit of smoking or drinking and 28 (93.3%) do not have the habit of smoking or drinking alcohol.

SECTION-II: COMPARISON OF POST-TEST LEVEL OF ORAL MUCOSITIS AMONG EXPERIMENTAL AND CONTROL GROUP.

Table –4.5 Frequency and percentage distribution of post test level of oral mucositis among chemotherapy patients in in experimental and control group.

N=60

Level of Oral Mucositis	Experimental group		Control group	
	f	%	f	%
None (0)	23	77	17	57
Mild (1)	7	23	7	23
Moderate (2)	0	0	6	20
Severe (3)	0	0	0	0
Intravenous Feeding (4)	0	0	0	0
Total	30	100	30	100

The above table-4.5 depicts that in the experimental group 23 (77%) of them did not develop oral mucositis, 7 (23%) of them had mild level of oral mucosits and none of them had moderate, severe or intravenous feeding level of oral mucositis. In control group none of the patients had sever or intravenous feeding level of oral musocitis, 6 (20%) of them had moderate level of oral mucositis, 7 (23%) of them had mild oral mucosits and 17 (57%) of patients did not develop oral mcositis.

Furthermore in experimental group, only 23% of patients developed oral mucositis, whereas in control group 43% of patients developed oral mucositis.

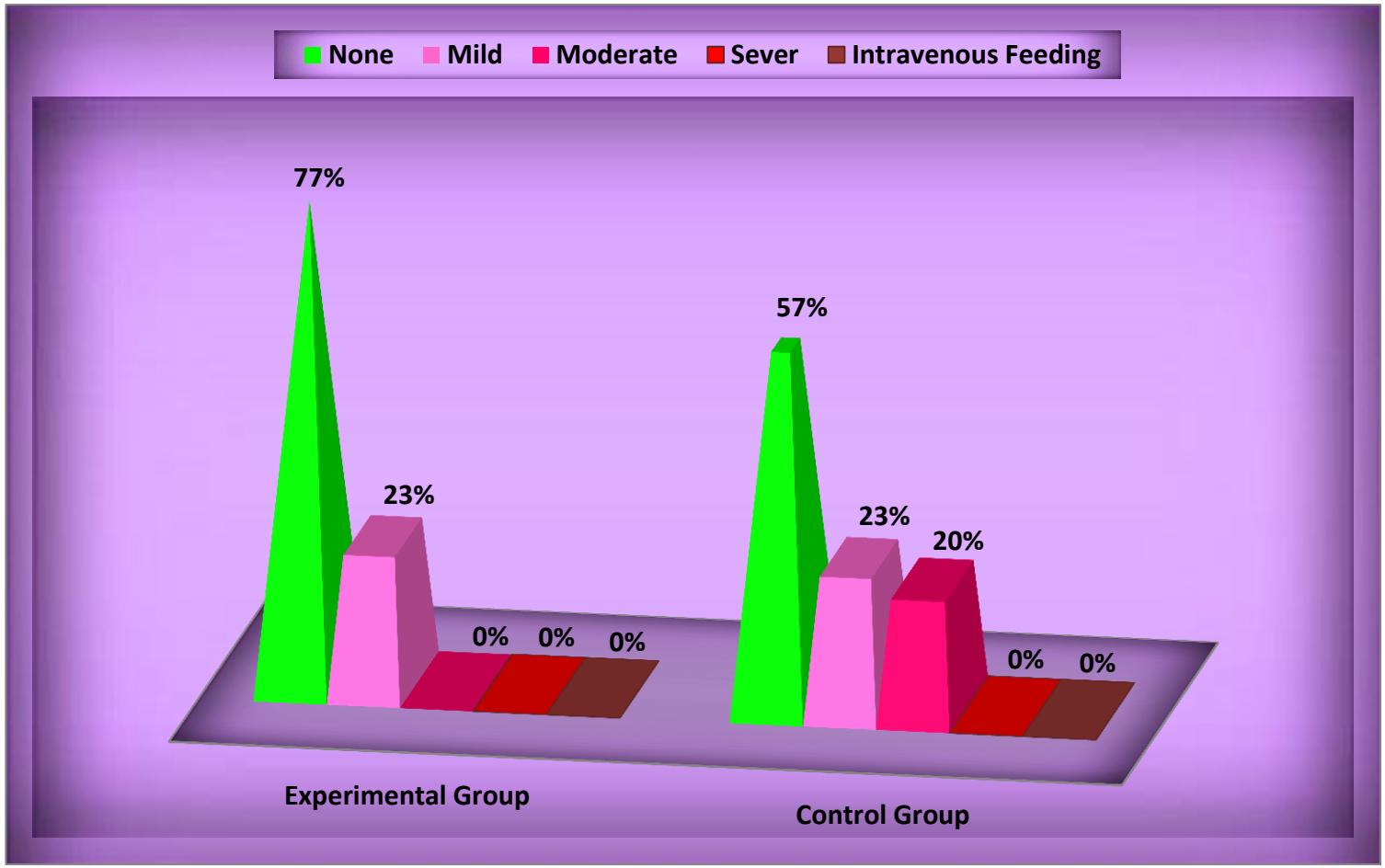


FIGURE 6: FREQUENCY OF LEVEL OF ORAL MUCOSITIS AMONG CHEMOTHERAPY PATIENTS

SECTION-III: EFFECTIVENESS OF POMEGRANET POPSICLES ON THE LEVEL OF ORAL MUCOSITIS AMONG EXPERIMENTAL AND CONTROL GROUP

Table 4.6 Paired 't' test value of the oral mucositis score of chemotherapy patients among experimental and control group

N=60

S.No	Variable	Experimental Group (n=30)		Control Group (n=30)		df	*t*	*p value*
		Mean	**SD**	**Mean**	**SD**			
1.	Pomegranate Popsicles	0.23	0.430	0.63	0.809	58	2.392	0.02*****

***** The result is significant at $p < 0.05$.

The above table 4.6 shows the effectiveness of pomegranate popsicles on inflammation of the oral mucosa among chemotherapy patients. The paired 't' test gave a 't' value of 2.392, at df =58, the p value was 0.02 which is significant at $p < 0.05$ level.

SECTION-IV: ASSOCIATION OF LEVEL ORAL MUCOSITIS AMONG EXPERIMENTAL AND CONTROL GROUP WITH THE SELECTED DEMOGRAPHIC VARIABLES.

Table 4.6 Association of post test levels of oral mucositis among experimental and control group with the selected demographic variables

N=60

S.No	Demographic variables	Level of Oral Mucositis			Chi-Square	p value
		None	Mild	Moderate		
1.	**Age (in years)**				0.168	0.919 NS
	a) 30-39	7	-	-		
	b) 40-49	11	2	1		
	c) 50-60	22	12	5		
2.	**Sex**				0.082	0.774 NS
	a)Male	8	6	3		
	b)Female	32	8	3		
3.	**Educational Status**				0.693	0.707 NS
	a) Un Educated	-	-	-		
	b) Primary School	3	-	2		
	c) High School	15	7	3		
	d) Graduate	22	7	1		
4.	**Occupation**				2.466	0.291 NS
	a) Home Maker	28	9	-		
	b) Government	-	-	-		
	c) Private	9	4	3		
	d) Business	3	1	3		
5.	**Type of Activity**				4.498	0.106 NS
	a) Sedentary	8	-	1		
	b) Moderate	31	14	5		
	c) Heavy	1	-	-		

6.	**Family H/o Cancer** a) Yes b) No	 4 36	 5 9	 2 4	1.002	0.317 NS
7.	**Mouth Wash** a) Yes b) No	 5 35	 2 12	 1 5	1.176	0.278 NS
8.	**Frequency of Brushing per day** a) None b) Once c) Twice d) Thrice	 - 7 33 -	 - 2 12 -	 - 2 4 -	1.002	0.317 NS
9.	**Item used for brushing** a) Tooth Powder b) Toothpaste c) Charcoal Powder d) Chewing Stick	 - 40 - -	 - 13 1 -	 - 3 3 -	4.13	0.041*
10.	**Frequency of Gargle per day** a) None b) Once c) Twice d) Thrice	 14 5 19 2	 5 5 4 -	 3 2 1 -	4.727	0.193 NS
	Dietary Pattern a) Vegetarian b) Non Vegetarian	 9 31	 4 10	 2 4	0.800	0.371 NS
	Eating Sweets a) Never b) Everyday c) Few times a week d) Few times a month	 7 - 16 27	 5 - 6 3	 2 - 2 2	2.589	0.274 NS

	Chat items in diet					
	a) Never	5	3	-		
	b) Everyday	1	-	-	12.051	.007*
	c) Few times a week	28	7	6		
	d) Few times a month	6	4	-		
	Fizzy Drinks					
	a) Never	26	12	4		
	b) Everyday	-	-	-	1.206	0.547 NS
	c) Few times a week	8	-	1		
	d) Few times a month	6	2	1		
	Chewing Tobacco					
	a) Yes	1	8	5	1.491	0.222 NS
	b) No	39	6	1		
	Smoking or Drinking Alcohol					
	a) Yes	-	3	4	1.456	0.228 NS
	b) No	40	11	2		

* Significant at 0.05 level NS – Not Significant

This table shows the association between the level of oral mucositis and selected demographic variables of patients with cancer who are undergoing chemotherapy. The results showed that there was no significant association of the post-test level of oral mucositis and demographic variables such as Age, Sex, Education, occupation, type of activity, Family History of cancer, Use of Mouth wash, frequency of brushing, Item used for brushing, Frequency of gargle, Diet pattern, tobacco chewing, smoking and drinking. The results shows an association of item used for brushing and chat items with inflammation of oral mucosa, statically significant at $p<0.05$ level

CHAPTER-V
DISCUSSION

This chapter discusses the major findings of the study and reviews them in relation to finding from other studies.

The aim of the study was to assess the Effectiveness of Pomegranate Popsicles on Inflammation of the oral mucosa among Patients on Chemotherapy in a Selected Hospital at Chennai.

In this study Quasi experimental, post test only control group design was adopted. Sixty sample were selected by purposive sampling, and the samples were assesses and those fulfilling the inclusion criteria were selected in experimental and control groups. Demographic data was collected by using a questionnaire. Intervention with pomegranate popsicles was given to the patient in the experimental group, the control group followed the standard hospital care with fresh water mouth wash. Post test was conducted on the seventh day to assess the level of oral mucositis using a W.H.O Oral Mucositis Scale. The data was organized and analyzed and the major results of the study are discussed according to the objectives.

MAJOR FINDINGS OF THE STUDY AND DISCUSSION

Majority of the samples were in the age group of 50 – 60 years (65%). Females were more affected by cancer than males (71.7%). 86.7% of patients were married where as 13.3% of them were widows. Most of the samples were Hindus (88.3%). About 50% of the samples were graduates. About 66.7% of patients were home makers. 83.3% of patients were sedentary workers.

All the patients had a monthly family income of more than Rs.15, 000. per month. 18.3% of patients had relatives diagnosed with cancer. And 15% of patients had relatives who underwent chemotherapy.

Regarding oral hygiene, 15% of patients used oral mouth wash. Majority of the patients, 81.7% had the habit of brushing twice daily. About 6.7% of patients used charcoal for brushing the teeth. About 40% of the patients had the habit of gargle thrice a day.

Considering Dietary Pattern, 75% of the patients were non vegetarians. 40% of patients had the habit of eating sweets few times a week. 68.3% of patients used chat items in their diet few times a week. Majority of patients to 70% never take fizzy drinks. Considering habits, 23.3% of patiemt chew tobacco. 11.7 % of patients had the habit of drinking and smoking.

The results were supported by a study conducted by **J. M. de Rijke et.al** on Age-specific differences in the diagnostics and treatment of cancer patients in the province of Limburg, the Netherlands. The diagnosis was confirmed that in 88% of the total patient population. 93% of cancer patients were of age category 50-59 years, 90% in 60-69 years and 83% in70.The study projection shows that majority or cancer patients were in 50-59 years of age group.

The findings of the study based on the objectives:

To evaluate the effectiveness of pomegranate popsicles on oral mucositis among patients receiving chemotherapy in experimental and control group.

Comparison of Frequency and Percentage Distribution

The analysis showed 77% of patients in experimental group of them did not develop oral mucositis, 23% of them had mild level of oral mucosits and none of them had moderate, severe or intravenous feeding level of oral mucositis. In control group none of the patients had sever or intravenous feeding level of oral musocitis, 20% of them had moderate level of oral mucositis, 23% of them had mild oral mucosits and 57% of patients did not develop oral mcositis.

Furthermore, in experimental group only 23% of patients developed oral mucositis, whereas in control group 43% of patients developed oral mucositis. Thus patients were 20% less likely to develop oral mucositis when given pomegranate popsicles during chemotherapy.

This result was supported by **Cascinu S et.al** randomized study demonstrating the utility of oral cooling (cryotherapy) in the prevention of chemotherapy induced oral mucositis. Mucositis was significantly reduced by cryotherapy considering both the first cycle of therapy (the mean toxicity score for cryotherapy was 0.59 and it was 1.1 for the control group, $P < \text{or} = 0.05$) and all the chemotherapeutic courses (the mean toxicity score for cryotherapy was 0.36 when it was 0.69 for the control group, $P < \text{or} = 0.05$).

In conclusion, the present study confirms that cryotherapy can prevent and decrease chemotherapy induced oral mucositis and should be recommended for patients receiving chemotherapy regimens.

Mean, Standard Deviation and Paired 't' test value

The study findings revealed that the paired 't' test gave a 't' value of 2.392, at df=58, the p value was 0.02 which is significant at $p < 0.05$ level. Hence the research hypothesis (H_1) was accepted.

This result is supported by **Karagözoğlu S et.al (2005)** study investigating the effect of oral cryotherapy on the development of chemotherapy-induced mucositis. According to Patient-Judged Mucositis Grading, the rate of mucositis is 36.7% in study group and 90.0% in control group, the difference between two groups being statistically significant ($P < 0.05$). According to Physician-Judged Mucositis Grading, the rate of mucositis is 10.0% in the study group and 50.0% in the control group, the difference between two groups being statistically significant ($P < 0.05$).

Hence pomegranate popsicles have a significant effect on preventing and reducing inflammation of the oral mucosa among chemotherapy patients.

The second objective of the study was to out find out the association between the post-test levels of oral mucositis among patients receiving chemotherapy with their selected demographic variables.

The results showed that there was no significant association of the post test level of oral mucositis and demographic variables such as Age, Sex, Education, occupation, type of activity, Family History of cancer, Use of Mouth wash, frequency of brushing, Item used for brushing, Frequency of gargle, Diet pattern, tobacco chewing, smoking and drinking. The results revealed an association of item used for brushing and chat items in diet with inflammation of oral mucosa, at $p<0.05$ level

Hence there is an association with respect to selected demographic variables. Hence the corresponding research hypothesis H_2: Stated earlier "There is a significant association between the post-test levels of inflammation of the oral mucosa among patients on chemotherapy with their selected demographic variables." was retained.

This result is supported by ***Dorothy M. Keefe et al (2008)*** study conducted on Updated clinical practice guidelines for the prevention and treatment of mucositis. The results from this study showed that what the patient used for brushing had a significant reduction in level of oral mucositis. When analyzed the association of demographic variables what is used for brushing showed a statistical significance in level of oral mucositis comparing before and after the intervention.

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CHAPTER – VI
SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

This chapter summarizes the findings, understanding and interpretation of results and recommendations that incorporate the implications such as nursing practice, nursing education, nursing administration, and nursing research. It also gives meaning to the results obtained in the study.

6.1 SUMMARY

A person diagnosed with cancer may undergo surgery, radiation or chemotherapy as a management of cancer, among which chemotherapy is the commonest treatment modality. Many oral complications arise as a side effect of chemotherapy, among these oral mucositis is a major nonhematologic complication of cytotoxic chemotherapy. Preventing a complication beforehand is much easier and less costly than treating it. In this context, cryotherapy (oral cooling using ice) has become a cheap and readily applicable method in preventing or decreasing oral mucositis developing due to chemotherapy. As ice cubes can be made readily available and cheaper, people undergoing chemotherapy may effectively use this in their due course of therapy. With enough scientific evidence supporting cryotherapy as the best treatment to prevent oral mucositis and recommendation for further research with frozen fruit juices, the investigator had an intense curiosity to assess the effectiveness pomegranate popsicles over oral mucositis among the patients receiving chemotherapy thereby undertaking this study.

The objectives of the study,

- ❖ To evaluate the effectiveness of pomegranate popsicles on oral mucositis among patients receiving chemotherapy in experimental and control group.

- ❖ To find out the association between the post-test level of oral mucositis among patients receiving chemotherapy with their selected demographic variables.

The research hypothesis,

H_1 – There is a significant difference in the post-tests level in inflammation of the oral mucosa among patients on chemotherapy between experimental and control group.

H_2 - There is a significant association between the post-test levels of inflammation of the oral mucosa among patients on chemotherapy with their selected demographic variables.

Review of literature was done related to:

1) Studies related to oral mucositis as a side effect of cancer

2) Studies related to the prevention of oral mucositis by cryotherapy

3) Studies related to pomegranate and its effect on cancer

The conceptual framework opted for this study was Widenbach‟s helping art of clinical nursing theory. Quasi experimental approach was used with post test only control group design, with 30 samples in experimental and control group each. Non probability, purposive sampling was used and the study was conducted at Dr.Kamakshi Memorial Hospital, Chennai.

The tool consisted of structured questionnaire to elicit the demographic variables and WHO Oral Mucositis Scale was used to assess the level of

oral mucositis. The tool was validated by 5 experts and the validity of the tool was established. The reliability of the tool was found (r=0.8) by test retest method, and the tool was considered as fit for proceeding with pilot study.

A Pilot study was conducted to assess the feasibility, practicability of the study and six patients were selected who fulfilled the inclusion criteria, The intervention had an appreciable decrease in the level of oral mucositis among patients undergoing chemotherapy.

A total number of 60 chemotherapy patients who met the inclusion criteria were selected by non probability convenient sampling technique. The subjects in first and second week are taken as experimental group, the subjects in third and four week are taken as control group.

After getting the consent, the pomegranate popsicles were given to patients in experimental group. Routine hospital measures were followed for patients in control group. Post test level of oral mucositis was assessed by using the WHO Oral Mucositis Scale on seventh day and data was analysed using descriptive and inferential statistics.

The findings from the post test showed that 23% of patients in experimental group developed oral mucositis while 43% of patients in control group developed mild and moderate oral mucositis. So the incidence of oral mucositis was 20% higher in patients who did not get cryotherapy with pomegranate popsicles.

The analysis revealed that mean and standard deviation of post test level of oral mucositis of chemotherapy patients in experimental and control group the mean value of 0.23 with SD 0.23 and the mean value of 0.63 with SD 0.809 of post test level in control group projects ‘t’ value as

2.392 is statistically significant at $p < 0.05$ level. Hence the stated research Hypothesis (H_1) was accepted.

There was a significant association in post test level of oral mucositis in experimental group with what the patients intake of chat items in the diet, but there is no association with other demographic variables like age, sex, marital status, religion, etc. Hence the stated research Hypothesis (H_2) was retained.

6.2 CONCLUSION:

Oral Mucositis is one of the most common side effect of chemotherapy, it adversely affects the course of chemotherapy and the patients quality of life as well. This study highlighted the effectiveness of Pomegranate Popsicles in reducing oral mucositis among chemotherapy patients, and thereby improves the quality of life. As popsicles can be made easily and is readily available, patients can effectively use this method to prevent oral mucositis. Nurses can promote the use of pomegranate popsicles, thus promoting the patients quality of life and prognosis of the disease.

Study findings showed that pomegranate popsicle is a more effective in reduction of oral mucositis among patients undergoing chemotherapy is a non-pharmacological, cost effective and simple approach in preventing oral mucositis

6.3 IMPLICATIONS

This section of the research report that focuses on Nursing implications, which includes specific suggestions for Nursing practice, Nursing education, Nursing administration and Nursing research.

NURSING PRACTICE

- Oral cooling by cryotherapy is a nursing intervention that is well-tolerated by patients and easily implemented by nurses.
- Nurses should get the co-operation of the diet kitchen team and resources in preparation, transportation and use of Pomegranate Popsicles.
- Nurses should create awareness and motivate others in the team to use this approach in reducing the oral mucositis among chemotherapy patients.
- Teach the staff nurses about the effectiveness of pomegranate popsicles to reduce oral mucositis among chemotherapy patients.
- Nurses can give health education to the patients on oral mucositis and how it can be prevented by pomegranate popsicles.

NURSING EDUCATION

- A Continuing nursing education program can be arranged on cryotherapy with popsicles and chemotherapy induced oral mucositis.
- Pomegranate Popsicles is a non pharmacological intervention that can be integrated with Nursing curriculum.
- In service education can be given to staff Nurses and faculty members regarding cryotherapy and chemotherapy induced oral mucositis.
- Nursing students from various levels must be educated about oral cryotherapy in order to practice in the clinical settings.

- A nurse educator should encourage the students for effective utilization of research evidence based practice related to oral cryotherapy by pomegranate popsicles on chemotherapy patients.

NURSING ADMINISTRATION

- The Nurse administrator should create awareness of importance and benefit of oral cryotherapy with pomegranate popsicles.
- Oral cryotherapy with pomegranate popsicles is one of the cost effective intervention for oral mucositis which develops due to chemotherapy, so arrangements can be made for it preparation and use in chemotherapy department.
- Nurse administrators can get the co-operation of the dietitians in preparation, storage and transport of popsicles for patients in chemotherapy ward.
- Nurse administrator can instruct and encourage their subordinates to utilize this as a nursing intervention in their clinical settings.
- Arrange and conduct workshop, conference and seminars on oral mucositis and its management by oral cryotherapy with pomegranate popsicles.

NURSING RESEARCH

- As a nurse researcher, promote more research on cryotherapy for oral mucositis among chemotherapy patients.
- Studies related to using frozen fruit juices are rare in Nursing field. So the Nurse researcher can conduct similar studies related to cryotherapy with other fruit juices. This will help the Nurses to promote to Evidence Based Practice in this aspect.

- Disseminate the findings of the research through conferences, seminars and publishing in nursing journal.

- Promote effective utilization of research findings on management of oral mucositi by cryotherapy with pomegranate popsicles in chemotherapy wards.

6.4 RECOMMENDATIONS

- The same study can be done with large sample size so that the results can be generalized.

- Comparison of frozen juices for cryotherapy with other types of management for chemotherapy induced oral mucositis can be conducted.

- Studies can be conducted to assess the Knowledge and Practice of Medical and Paramedical personnel's regarding cryotherapy with frozen juices.

- Studies can be conducted to assess the awareness and practice n cryotherapy with frozen juices on oral mucositis induced by chemotherapy.

- The same study can be done on different settings on larger number of samples.

- Studies to assess the quality of life improved by pomegranate popsicles.

- Studies can be done to assess effect of pomegranate popsicles on continuous three cycles of chemotherapy.

- A similar study can be done by changing the fruit juice and checking the patient's preference.

6.5 LIMITATIONS

- The investigator found difficulty in getting adequate literature related to the study related to fruit juice oral cryotherapy.
- The pomegranate popsicles had to be prepared freshly everyday.
- The investigator faced difficulty in transport of the popsicles.
- The preparation of pomegranate popsicles was a time consuming process.
- Due to time constrains, the investigator was unable to take large samples for the study.
- Due to time constraint, investigator could not assess other cycle of chemotherapy.

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DEMOGRAPHIC VARIABLES

Part – I (GENERAL INFORMATION)

1. Age in years
    a) 30-39
    b) 40-49
    c) 50-60
2. Sex
    a) Male
    b) Female
3. Marital status.
    a) Married
    b) Unmarried
    c) Widower
    d) Divorced
4. Religion
    a) Hindu
    b) Muslim
    c) Christian
    d) Others
5. Educational status
    a) Un Educated
    b) Primary school
    c) High school
    d) Graduate
6. Occupation
    a) Home Maker
    b) Government
    c) Private
    d) Business

7. Type of Activity
    a) Sedentary
    b) Moderate
    c) Heavy
8. Monthly family income
    a) Below Rs.8000/-
    b) Rs.8000 – 10000/-
    c) Rs.10000 – 15,000/-
    d) Above Rs.15,000
9. Does any of your family members have cancer
    a) Yes
    b) No
10. Is any of your family member taking chemotherapy
    a) Yes
    b) No

Part II (ORAL HYGIENE)

11. Do you use mouth wash solution
    a) Yes
    b) No
12. How many times do you brush in a day
    a) I don't brush
    b) Once
    c) Twice
    d) Thrice
13. What do you use for cleaning your teeth?
    a) Tooth Powder
    b) Toothpaste
    c) Charcoal Powder
    d) Chewing Stick

14. How often do you gargle?
    a) I don't gargle
    b) Once a day
    c) Twice a day
    d) Thrice a day

Part III (DIET)

15. Dietary Pattern
    a)Vegetarian
    b)Non-Vegetarian

16. How often do you eat sweets?
    a) Never
    b) everyday
    c) few times a week
    d) few times a month

17. How often do you include chat items in your diet?
    a) Never
    b) everyday
    c) few times a week
    d) few times a month

18. How often do you have fizzy drinks?
    a) Never
    b) everyday
    c) few times a week
    d) few times a month

Part IV (HABITS)

19. Do you have the habit of chewing tobacco?
    a)Yes
    b)No

20. Do you have the habit of smoking or drinking alcohol?
    a)Yes
    b)No

W.H.O - ORAL MUCOSITIS SCALE

GRADE	DEFINITION
0	None
1	Soreness ± Erythema
2	Erythema, ulcers, and patient can swallow solid food
3	Ulcers with extensive erythema and patient cannot swallow solid food
4	Mucositis to the extent that alimentation is not possible

Patient Score: Grade ☐

SCORING KEY

W.H.O - ORAL MUCOSITIS SCALE

GRADE	SCORE
0	None
1	Mild
2	Moderate
3	Severe
4	Intravenous Feeding

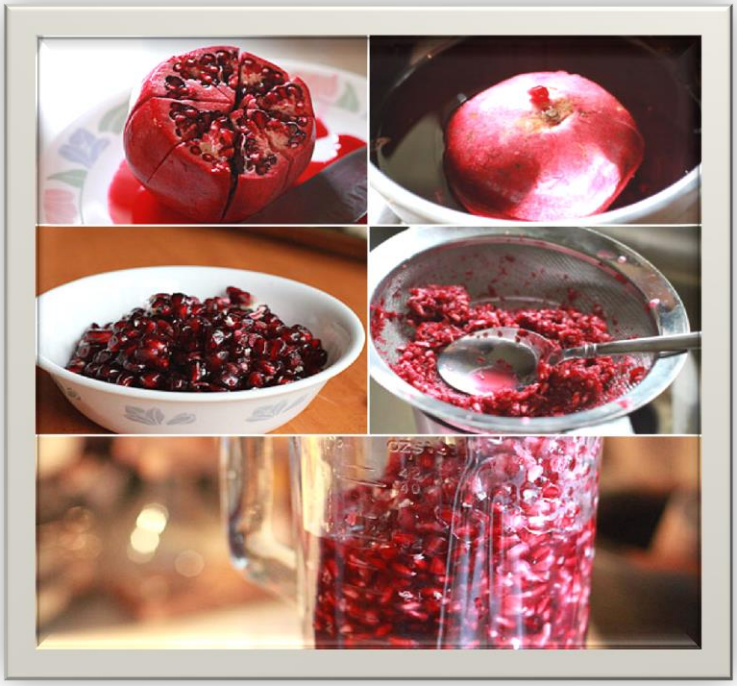
POMEGRANATE POPSICLES

Preparation of Pomegranate Popsicles

Step1: Selecting the pomegranates. (Punica granatum – Ruby variety) This variety has small soft seed and medium sized arils. Its deep red colour makes it appealing to the patients.

Step2: Deep red pomegranates are washed thoroughly and then peeled.

Step3: The grains are separated in a bowl and then put in a blender. They are allowed to blend for 2 seconds. (Blending for 2 seconds peals the pulp, extracting the juice but leaving the seeds unbroken. Thus making a fine nectar rather than making the juice whitish and milky.)



Step4: After blending, the juice is filtered with a pimary strainer and then a secondary strainer to remove any fine particles.

Step5: The juice is further fine filtered using a jelly bag, leaving behind a fine neactar of deep red pomegranate juice.

Step6: The juice is then gently poured into the standard ice cube maker
of (4x2.5) size.

Step8: The ice cube maker is sealed with an aluminiam foil and 7 cm ice cream sticks are placed in the center of each cubical space, and kept to freez for 2-3 hours.

Step9: Once its frozen the pomegranate popsicles are ready to be served to chemotherapy patients.

PERMISSION LETTER FROM INSTITUTIONAL ETHICS COMMITTEE

VELS

VENKATESWARA NURSING COLLEGE

(A unit of **VELS Group**, Pallavaram)

Approved by Indian Nursing Council, (Cert. No. 18-29/3458-INC) and Tamil Nadu Nurses & Midwives Council
Affiliated to The Tamil Nadu Dr. M.G.R. Medical University

Thalambur, Off Old Mahabalipuram Road, Near Navalur, Chennai - 603 103
Phone : (91-44) 3253 7098 / 2743 5060 Fax : (91-44) 2743 5059

INSTITUTIONAL ETHICS COMMITTEE
CERTIFICATE OF APPROVAL

TO,

Mr. Chandra Rajan Enoch Snowden Rose,
M.Sc (N) I year,
Venkateswara Nursing College,

Dear Mr.Chandra Rajan Enoch Snowden Rose,

The Institutional Ethics Committee of Venkateswara Nursing College reviewed and discussed your application for the approval of the proposal entitled **"A Study to Assess the Effectiveness of Pomegranate Popsicles on Inflammation of the oral mucosa among Patients on Chemotherapy at a selected Hospital in Chennai".**

The following members of Ethics committee were present in the meeting held on 04.03.14 at Venkateswara Nursing College, Chennai-600 130.

1.	Prof. Kamala Subbian	- Principal, Venkateswara Nursing College,	- **Chair Person**
2.	Dr. N. Jaya	- Professor & HOD, OBGN & Research,	- **Member Secretary**
3.	Dr. G. Ilangovan	- Medical Director, Shri Isari Velan Mission Hospital	- **Member**
4.	Dr. Lodd Mahendra	- Principal, SVDC&H	- **Member**
5.	Dr. R.S. Rajalakshmi	- Professor & HOD, SVDC&H	- **Member**
6.	Dr. R. Sivakumar	- Professor	- **Member**
7.	Mr. C. Saravanan	- Legal Expert	- **Lawyer**
8.	Dr. P. Senthil Selvam	- Principal, School of Physiotherapy	- **Member**
9.	Mr. V. S. Ravi	- AO - SVDCH & VNC	- **Member**
10.	Mr. D. Sathish	- SIVMH	- **Social Science**

We approve the proposal to be conducted in its presented form

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

City Admn. Office : # 521/2, Anna Salai, (Opp. G.R. Complex), Nandanam, Chennai - 600 035.
Phone / Fax : (91-44) 2431 5541 / 2431 5542

PERMISSION LETTER FROM DR.KAMAKSHI MEMORIAL HOSPITAL

Phone: 044 – 66 300 300/301/302

Extension: 113

E-Mail ID: academicboard@drkmh.com

Website: www.drkmh.com

Expanding the Frontiers of Healthcare

கல்வித்துறை,
டாக்டர்.காமாட்சி நினைவு மருத்துவமனை,
எண்.1, ரேடியல் சாலை, பள்ளிக்கரணை,
சென்னை - 600100, தமிழ்நாடு.

ACADEMIC SECTION
Dr.Kamakshi Memorial Hospital,
No.1, Radial Road Pallikkaranai,
Chennai – 600100, Tamil Nadu

NURSING CLINICAL POSTING – GRANT OF PERMISSION

Ref.No.:— 14A/NCCP-05/2014 / Dated:— 13.09.2014

To
THE PRINCIPAL, [CODE:005]
VENKATESWARA NURSING COLLEGE,
THALAMBUR, OFF OLD MAHABALIPURAM ROAD,
NEAR NAVALUR, CHENNAI-603103,
TAMIL NADU, INDIA
PHONE: (044) 32537098 / 27435060

Sir / Madam,

SUB:— ACADEMIC – Study / Dissertation / Project Guidance by the Faculty of Dr.Kamakshi Memorial Hospital Pvt. Ltd. for the Post Graduate Nursing Cándidates from Venkateswara Nursing College, Thalambur, Chennai – Permission – Reg.

REF:— Your Letter No.161/14 dated 11.09.2014.

Kindly refer the letter(s) cited above.

We would like to inform you that the candidate(s) of your College/Institution is/are permitted to get Project / Study / Dissertation Guidance in our institution.

Name of the Candidate	:	**CHANDRA RAJAN ENOCH SNOWDEN ROSE**
Study Title	:	"A Study to assess the effectiveness of Pomegranate Popsicles on Inflammation of Oral Mucosa among Patients on Chemotherapy in a selected hospital at Chennai"
Under the Guidance of	:	Dr.P.RAJKUMAR (Surgical Oncologist)

Instructions to the Candidates:

1. Candidates should abide the rules and regulations of Hospital Administration.
2. Candidates' attitude and discipline should be exemplary.
3. To maintain good relations with all and particularly with your Supervisor(s).
4. To be punctual and regular. In case of difficulties, approach your Supervisor.
5. Always to carry Identity Card and produce the same on demand.
6. Do not disturb the workers in their work
7. Do not record any information or copy out any drawing or part thereof without the permission of Supervisors.

Contd…2…

PERMISSION LETTER FROM DR.KAMAKSHI MEMORIAL HOSPITAL

---2---

8. Do not disturb the workers in their work
9. Do not record any information or copy out any drawing or part thereof without prior and proper permission.
10. Do not operate any instrument / machine / apparatus without specific instruction of your Supervisor and without his supervision.
11. Do not carry any valuables.

Nominal Fee: Rs.2250/- (Rupees Two Thousand and Two Hundred and Fifty only)

This Permission Order is VALID for THIRTY (30) DAYS only from the Date of Commencement of Study / Project Work / Thesis / Dissertation.

Date of Commencement: **15.09.2014 (Monday)**

The receipt of this communication may kindly be acknowledged at the earliest.

Yours faithfully

Prof.(Dr.).K.THAYALAN.,M.Sc.,Dip.R.P.,Ph.D.,
ACADEMIC OFFICER

Copy forwarded for the information to—
(1) Nursing Superintendent
(2) Stock File

DETAILS OF FEE PAYMENT:

Amount Paid (on the first day) : Rs. 2250 /-

Date of Payment : 15/9/14

valid upto : 14/10/14

THIS ORIGINAL COMMUNICATION / PHOTOCOPY OF THE SAME SHOULD BE PRODUCED ON THE FIRST DAY OF TRAINING SESSION BY THE FACULTY / STAFF OF YOUR INSTITUTION WHO ACCOMPANY ALL THE CANDIDATES.

CERTIFICATE OF CONTENT VALIDITY

CERTIFICATE OF CONTENT VALIDITY

This is to certify that the tool developed by **Mr. Chandra Rajan Enoch Snowden Rose,** M.sc Nursing II[nd] year student of VENKATESWARA NURSING COLLEGE, Thalambur, Chennai- 600130. For the study "**A STUDY TO ASSESS THE EFFECTIVENESS OF AMONG PATIENTS ON CHEMOTHERAPY IN A SELECTED HOSPITAL AT CHENNAI**", validated by the undersigned and he can proceed with this tool to conduct the main study.

Signature: P. Rajkumar

Name : Dr. P. RAJKUMAR

Seal :

Date : 05.09.2014

Dr. P. RAJKUMAR
Medical Superintendent
Dr. Kamakshi Memorial Hospital Pvt. Ltd.
1, Radial Road, Pallikaranai, Chennai-100.

CERTIFICATE OF CONTENT VALIDITY

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Signature: R. Rallu.

Name : Dr. Prof. Rama Sambasivam

Seal :

Date :

PRINCIPAL
MOHAMED SATHAK
A.J. COLLEGE OF NURSING
34, RAJIV GANDHI ROAD (OMR)
IT HIGHWAY, SIRUSERI, CHENNAI-603103

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Signature:

Name : PROF STELLA SUJANA KUMARI

Seal :

PROFESSOR CUM PROGRAMME CO - ORDINATOR
M.Sc (N) in Medical Surgical Nursing
(Cardiovascular and Thoracic Nursing)
Rajiv Gandhi Salai, Kelambakkam,
Kanchipuram District - 603 103.

Date : 10/09/14

RESEARCH CONSENT FORM-ENGLISH

CONSENT FORM

Here by I Mr./Mrs._____Express my consent whole heartedly to be the subject of the study is "A Study To Assess The Effectiveness Of Pomegranate Popsicles On Inflammation Of The Oral Mucosa Among Patients On Chemotherapy In A Selected Hospital At Chennai."
I have been explained about pomegranate popsicles. It has been informed that the procedure is not going to cause any harm to me. I understand that all the personal information about me will be maintained confidentially and I can withdraw from the study at any time where I feel uncomfortable. I am willing to participate in your study.

Consent:
The above information regarding the study has been read by me and has been explained to me by the investigator from the Venkateswara Nursing College. Having understood the same, I hereby give my consent to participate in the study. I affixing my signature to indicate my consent and willingness that I will cooperate in this study.

Name of the subject:

Signature of the subject:

Date:

Name of the researcher:

CERTIFICATE OF ENGLISH EDITING

CERTIFICATE OF ENGLISH EDITION

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the dissertation work **"A STUDY TO ASSESS THE EFFECTIVENESS OF POMEGRANATE POPSICLES ON INFLAMMATION OF THE ORAL MUCOSA AMONG PATIENTS ON CHEMOTHERAPY IN A SELECTED HOSPITAL AT CHENNAI."** Done by Mr.Chandra Rajan Enoch Snowden Rose, M.Sc(N) II year, Venkateswara Nursing College, Thalambur, Chennai-600130, has been edited by me and the use of English in this dissertation is found appropriate.

GOVT. BOYS HR. SEC. SCHOOL * THIRUKKALUKUNDRAM *

10.2.15

S. JANARTHANAN
M.Sc.,M.Ed.,M.Phil.,
HEADMASTER
Govt.Boys Hr.Sec.School
Thirukkazhukundram-603109
Kancheepuram Dist.

Signature